Exhibit 21

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACETAMINOPHEN – ASD-ADHD PRODUCTS LIABILITY LITIGATION	)	MDL No. 3043
	)	Case No. 1:22-md-03043-DLC
THIS DOCUMENT RELATES TO: All Cases, 1:22-md-03043	)	JUDGE DENISE COTE

FRIDAY, AUGUST 11, 2023

CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

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Videotaped deposition of Brandon Pearson, MS, Ph.D., held at the offices of Lanier Law Firm, 126 East 56th Street, New York, New York, commencing at 8:44 a.m. Eastern, on the above date, before Carrie A. Campbell, Registered Diplomate Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri, Kansas, Louisiana & New Jersey Certified Court Reporter.

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VIDEOGRAPHER: We are now on the record. My name is Jonathan Juarez. I am a legal videographer for Golkow Litigation Services.

Today's date is August 11, 2023, and the time is 8:44 a.m.

This deposition is taking place at 126 East 56th Street, New York, New York, in the matter of Acetaminophen (Tylenol) Products Liability Litigation.

The deponent is Brandon Pearson.

All counsel will be noted on the stenographic record.

The court reporter is Carrie Campbell and will now swear in the witness.

BRANDON PEARSON, MS, Ph.D., of lawful age, having been first duly sworn to tell the truth, the whole truth and nothing but the truth, deposes and says on behalf of the Defendant Johnson & Johnson, as follows:

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DIRECT EXAMINATION
QUESTIONS BY MR. PADGETT:
Q. Good morning.
A. Good morning.
Q. Can you state your full name for the record, please?
A. Brandon Lance Pearson.
Q. Okay. And you have a Ph.D.?
A. I do.
Q. Okay. Have you even been deposed before?
A. I have not been deposed before.
Q. Okay. Just a quick rundown of some basic ground rules.
You understand that the oath you just took is the same one as if you were in a court of law?
A. I do understand this.
Q. Okay. And not a marathon session. We'll probably take breaks every 60 to 90 minutes.
Does that sound good to you?
A. I understand.
Q. Okay. And probably the number one rule today is that -- I'm going to make a

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deal. I'm going to try not to start a question before you finish your answer, and in return, hopefully you'll not start to answer until I'm done with my question.
Does that sound like a fair deal?
A. That's fair.
Q. Okay. Did you bring any documents with you in the room today?
A. I have a copy of my expert report, my amended expert report, and with us we have copies of the studies that were reviewed as part of my expert report.
Q. When you say -- so all of the studies that you have with you, and I saw a box brought in, are studies that are discussed in your expert report?
A. The studies that were a component of the weight of evidence for the levels of evidence.
Q. I believe that was like 29 mouse and rat studies?
A. That's the approximate number that I recall, yes.
Q. Okay. Any other studies beyond

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those that were part of your weight of analysis in your expert report?
A. I do not believe we brought anything in addition to that.
Q. Okay. Are there any notes -- any of your notes on those studies that you brought with you in this room today?
A. No.
Q. Okay. They're clean copies?
A. Yes.
Q. Okay. At a break, is it -- we may take a peek at them.
MS. HUNT: Be my guest.
QUESTIONS BY MR. PADGETT:
Q. Okay. Any other documents that you brought with you today, other than your report and those studies you just discussed?
A. No.
(Pearson Exhibit 64 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Okay. I'm going to hand you what's been marked, Dr. Pearson, as Exhibit Number 64.
Do you recognize that document?

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A. Yes.
Q. Okay. And that is your July 19, 2023 invoice for your work in this case, correct?
A. That appears to be what this is.
Q. And this will kind of -- may short-circuit some of my questions.
There's a reference down there for 6/14 and a description of your activities that day.
Do you see that? June 14?
A. Yes, there's a couple of lines that say 6/14.
Q. Oh, okay. The first one, I'm looking at.
A. Okay.
Q. You reference there a 30-minute morning meeting with Amanda Hunt, and that's counsel sitting next to you, right?
A. Yes.
Q. But then it says 1:45-minute meeting with Dr. Cabrera and 1:15-minute meeting with Dr. Louie to discuss contents of expert reports.

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Was counsel present for the meeting -- meetings with Dr. Cabrera and Dr. Louie?
A. Yes.
Q. Okay. Have you had any meetings or Zoom -- Zooms or calls with plaintiffs' other named experts in this case in which counsel was not present?
A. Are you asking about Dr. Cabrera or Dr. Louie specifically or other --
Q. No, you've already clarified that -- any of them.
A. Any other expert reports involved in this case or these specific expert reports?
Q. No. There's four other experts named: Dr. Cabrera, Dr. Baccarelli, Dr. Louie and Dr. Hollander, right?
A. So Dr. Baccarelli I would have had meetings with independent of counsel.
Q. And did you have meetings with him discussing this case?
A. No.
Q. Did you have meetings with any

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other of the named experts we just went through about your work on this case or your expert report or their expert reports in the absence of plaintiffs' counsel?
A. No.
Q. Okay. Have you had any written communications with any of plaintiffs' other named experts in this case in which plaintiffs' counsel were not copied or somehow address -- addressees?
A. Could you -- could you state that again please?
Q. Have you had any written communications with any of the other named plaintiffs' counsel in this case involving your work on this case or your expert reports or their expert reports that did not include plaintiffs' counsel?
MS. HUNT: Object to form. I think you said plaintiffs' counsel and then plaintiffs' experts.
MR. PADGETT: Thank you.
Just -- I want to go back to the -- I understand you're clarifying, but there is a strict rule on

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objection to form only. But he could have clarified that if he didn't understand.
QUESTIONS BY MR. PADGETT:
Q. Can you -- I'll rephrase.
Have you had any written communications with any of other -- plaintiffs' other disclosed experts in this case regarding your work on this litigation, your expert report or their expert reports, in which plaintiffs' counsel was not involved?
A. Not to my recollection. If that did exist, it would have been produced.
Q. In response to the request for production that was part of your deposition notice?
A. Yes. But as I stated, I don't believe that exists.
Q. Okay.
A. I don't believe any of that correspondence exists.
Q. How did you initially get involved in this case, Dr. Pearson?
A. I was contacted by Amanda

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directly.
Q. And that was your first contact about this litigation?
A. Correct.
Q. And when was that contact first made?
A. If my memory serves, it was approximately February of this year? Or 2022. Sorry, my -- yeah, February.
Q. February of this year? 2023?
A. Sorry, no. February of 2022.
It would be in the e-mails that were produced.
Yeah, that timeline might -- I'm a little shaky on the line right now, but --
Q. So -- sorry.
A. Yeah. It would have been -- I remember the month was February. Yeah, it would have been -- sorry.
February of 2022 I was initially contacted. I didn't start working with the plaintiffs' attorneys until, I believe, November, which, yeah, that would have had to have been 2022. It's 2023 now.

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Q. So you were initially contacted about this case in February of 2022, about 16 months ago?
A. That's my recollection.
Q. When was -- and you were coauthor on a paper, a study article, that was published, the Baker 2023 study; is that right?
A. Yes.
Q. When was that article submitted for publication?
A. I do not recall the exact -- exactly when that paper was submitted for publication. I would have to look.
Q. Was it submitted for publication after February 2022?
A. No. I do not believe it was.
Q. And I believe we saw -- I totaled up your invoices, and it came, between your time and your hourly rate, which is $450, to about $61,000 invoiced so far.
Does that sound about right?
A. My hourly rate is $400.
Q. Oh, sorry.
A. And I haven't tallied the total

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amount, but that number is probably not outside the realm of possibility.
Q. So the last time entry I saw on your invoice was June 28.
How much more time have you spent working on this litigation since June 28?
A. I haven't sat down and calculated that number.
Q. Can you give me an estimate since June 28?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: In the month of July and now into August, I would estimate, I mean, many dozens of hours.
Somewhere between 50 and a hundred, I would estimate.
QUESTIONS BY MR. PADGETT:
Q. And how much time was spent working on your reply report of the 50 to 100 hours?
A. You're asking me about --
Q. Your rebuttal report.

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A. -- the rebuttal report?
Q. The rebuttal report. Sorry.
A. I can't say for certainty, but that would include that time. That 50 to 100 hours would include that time.
(Pearson Exhibit 65 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, I'm going to hand you what's been marked as Exhibit 65, which I believe is the same thing as the report -- the amended report that you have in front of you.
Can you confirm that that is your -- a copy of your June 21 amended expert report in this case?
A. Yes.
(Pearson Exhibit 66 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. And I'm going to hand you also what's been marked as Exhibit 66 and ask you to confirm that that's your supplemental expert report relating to the Klein 2023 study.

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And a copy of that study is attached to your supplemental report, correct?
A. This appears to be the supplement in response to the Klein, et al., paper that was published, yes.
(Pearson Exhibit 67 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. And I'm going to hand you what's been marked as Exhibit 67 and ask you to confirm that that is your July 28, 2023 rebuttal report submitted in this case.
A. Yes, this appears to be that document.
Q. Okay. And I believe your CV is Exhibit A to your amended expert report, Exhibit 65.
Is the information on your CV regarding employment and publications current?
A. It was current as of the date that was on it, which was early June.
Q. Any changes in position or publications since early June 2023 with

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regard -- that you would put on your CV if you updated it?
A. Are you asking if there's anything to update to date -- to now?
Q. Yes.
A. Certainly there's things that would be updated, yeah.
Q. What about employment positions? Are you in the same employment as listed on your CV?
A. My employment is the same.
Q. Okay. What other changes -- do you have an updated version of your CV?
A. I do not have an updated version, no.
Q. So if you were asked to create a CV this coming Monday, what additional things would you put on there?
A. I'm on an editorial board for another journal, for the Journal of Scientific Reports. I was appointed to that -- to the editorial board of that journal. That's new.
I have another publication that was accepted in the journal Frontiers in

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Neuroscience that has to do with environmental exposures and mutations and neurodevelopmental disorder genes.
There's other things that I can't think of off the top of my head at the moment. That's just -- those are examples.
Q. The article that was just recently accepted for publication that you just mentioned, does that relate in any way to acetaminophen?
A. It has relevance for acetaminophen, but it doesn't study acetaminophen directly.
Q. Can you tell me a little bit more about that particular study?
A. That study evaluates how carcinogens in particular can mutate genes that are implicated in neurodevelopmental disorders.
So individuals in the field of genomics and psychiatric genomics consider familial genetic risk and how alleles that are implicated in neurodevelopmental disorders are inherited, but they by and large don't consider the fact that

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environmental exposures can also mutate those genes.
And this particular study has evaluated the fact that exposures can also mutate those genes, and the study has garnered a lot of support for the fact that those genes are vulnerable to exposures, including things that cause oxidative stress and DNA damage.
And acetaminophen causes a lot of oxidative stress and DNA damage, so in that sense it's relevant.
Q. I'm sorry. What type of environmental substances were reviewed in that study?
A. This particular study focuses on environmental carcinogens, so things like UV exposure, radiation, chemotherapeutic drugs, things of that nature. So things that we know can cause cancer.
Q. Who are the coauthors of that study?
A. So the lead author is Dr. Brennan Baker, who is also the lead author on some of the studies that are

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relevant to the acetaminophen work.
There's Dr. Wendy Chung, who I see is written on your notebook there, who is a geneticist and physician.
Q. Any others?
A. Yeah, there's a number of other coauthors.
There's a student -- a former student of mine, Mu Yang.
Sarah McLarnan, who is a current doctoral student of mine, is a coauthor.
Let me think about who else are coauthors on that study.
Jeremy Simon, who's a bioinformatician that I've worked with for a number of years, he's at Boston Children's Hospital now. Harvard Medical School.
I'm not recollecting the other coauthors of that study at the moment.
Q. And I think you indicated in -- likely get into this a bit later -- but you -- that the relevance to acetaminophen is oxidative stress.
You mentioned that; is that

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right?
A. Oxidative stress can be an indirect mutagen.
Q. And in what other respects, other than this oxidative stress being an indirect mutagen, as you put it?
A. That's the -- that's the relevance.
Q. Are you aware of any specific scientific research showing that acetaminophen is a mutagen through an oxidative stress mechanism?
A. I mean, I have unpublished data that shows that, but I don't have published data that shows that. There -- let me think for a moment.
Could you restate the question again?
MR. PADGETT: Can you...
(Court Reporter read back question.)
THE WITNESS: Most of the literature that's looked at mutagenic properties of acetaminophen has relied on assays such as the Ames test, and I

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believe such assays aren't really capable of studying the phenomena of direct mutagenesis in mammalian systems that I'm studying.
The Ames test is a -- is bacterial systems, procaryotic systems. I'm studying mammalian mutagenesis systems. It's not a relevant assay system for some of the phenomenon that I'm studying.
But on the other hand, this types -- type of research is in its infancy, so a lot more research that needs to be done.
QUESTIONS BY MR. PADGETT:
Q. The Ames test assay test results on acetaminophen are negative for mutagenicity, correct?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: My understanding is that a lot of the Ames test data are negative.
But I would like to take a moment to clarify some of my previous

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responses and say that there is substantial scientific evidence that acetaminophen causes substantial hydroxyguanosine damage, which is DNA damage.
QUESTIONS BY MR. PADGETT:
Q. At thera -- sorry, go ahead.
A. At therapeutic doses.
Q. At therapeutic doses?
A. At therapeutic doses.
Q. Which study is that?
A. I would have to go through the studies in more detail, but let me -- if you give me just a second.
There's recent study that shows a biomarker data that -- in cord blood studies that acetaminophen exposures are linked with 8-oxo hydroxyguanosine levels in cord blood. And preclinical data as well. There is hydroxyguanosine lesions associated with acetaminophen exposures in addition to that.
So the biomarker data supports this. And as I mentioned, that is DNA damage. It's a form of oxidative DNA damage.

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Q. Would you agree that pain or complications during labor can cause oxidative stress?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I'm not aware of literature that shows that pain or complications during labor causes hydroxyguanosine damage.
QUESTIONS BY MR. PADGETT:
Q. My question was about oxidative stress.
Are you aware of literature showing that pain or complications during labor can cause oxidative stress?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: I'd be happy to review any studies that you -- that you put in front of me that show me that, but I'm not aware of studies that show that pain or complications during labor that show hydroxyguanosine DNA damage.

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QUESTIONS BY MR. PADGETT:
Q. And again, you keep saying hydroxyguanosine, and I'm saying oxidative stress generally.
But -- so like my question is, are you aware of scientific literature showing that there -- the complications or pain during pregnancy can cause increased oxidative stress in a pregnant woman?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: Well, I think there's a problem with the question, because oxidative stress is a fairly diffuse term. It's kind of a very, very broad phenomenon.
It's like saying stress. What is stress? What is your objective definition? It's an imbalance of antioxidant versus prooxidant systems. So you have to have operational definitions of what oxidative stress is.
So if you can show me the specific studies you're referring to,

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I can evaluate that. But I don't know necessarily what you're referring to, so I can't evaluate that.
QUESTIONS BY MR. PADGETT:
Q. Okay. Well, just to follow up on that.
Stress can cause an imbalance of oxidative stress in antioxidant systems.
Do you agree with that?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Stress is a very poorly construed paradigm. I spent many years studying stress. I don't know what you mean by "stress."
QUESTIONS BY MR. PADGETT:
Q. In the way that you just used it and as it relates to imbalance of oxidated -- oxidative -- oxygen species and antioxidants.
A. I was using that as an example of how terminology is used without a precise definition.
So you're just saying that -- the example that you were giving before is

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that pain or complications during pregnancy can cause oxidative stress.
I was telling you that I don't know what you mean by oxidative stress. And I was saying hydroxyguanosine DNA lesions are a consequence of oxidative stress. That's a measurable, tangible consequence of oxidative stress that damages the DNA.
I -- we can -- that's operationalizeable. We understand what that is.
Q. Okay.
A. And it's DNA damage, which is what we're discussing.
Q. You mentioned you have unpublished data that shows -- what were you mentioning that you said you had unpublished data showing acetaminophen and oxidative -- an oxidative mutagen relationship?
A. Could you restate that question, please?
Q. You mentioned earlier that you have unpublished data that shows -- and I believe it was in response to a question about oxidative -- oxidative mutagen type of

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mechanism when we were talking about the -- your unpublished article has been accepted.
What is that unpublished data about?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Sorry, I didn't let you get your objection out.
I'm actually really glad you asked this, because it just reminded me. We actually have published data.
So in the Baker, et al., 2023 paper, there is actually data that shows that there's mutational activity in it. So in the RNAC data, it shows that there's DNA damage and mutation happening. So there's cell cycle disruption. There's p53 activation that shows you there's DNA damage and cell cycle disruption.
So it's not just our unpublished data. There's actually published data that shows there's DNA damage and cell cycle disruption.
Our unpublished data that we

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had shows, and you all have seen it in my production, that there's gamma-H2AX in tissue that's upregulated. There's 53BP1 in tissue that's upregulated. And you can see it.

There is -- so that's showing you there's DNA double-strand breaks in the tissue. It's showing you that there's oxidative DNA damage in the tissue, all caused by acetaminophen exposure prenatally.

QUESTIONS BY MR. PADGETT:

Q. Are any of those related to long genes?

A. This is -- this has nothing to do with long genes. This is independent of that data.

Q. And have any of the effects that you just mentioned been specifically correlated as being associated with mechanisms leading to ASD?

A. Are you asking me with reference to the mechanisms that I just discussed with the DNA damage and the oxidative stress?

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Q. Specific to acetaminophen. The series -- starting with gamma, the series like two or three that you mentioned.

Have any of those been specifically associated with -- as a mechanism leading to ASD?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: Well, as I've outlined in my expert report, the oxidative stress in the tissue, the DNA damage and the transcriptional effects that we've seen, are associated with -- and lead to transcriptional signatures that correspond with autism and other neurodevelopmental disorders.

Using Gene Set Enrichment Analysis and other bioinformatics tools, we see enrichment with autism spectrum disorder.

QUESTIONS BY MR. PADGETT:

Q. What do you mean by enrichment?

A. So, again, using bioinformatics tools, we see signatures that correspond to

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these particular neurodevelopmental disorders such as autism spectrum disorder. So there's concordance with and correspondence with those particular neurodevelopmental disorders.

Q. You say "signatures." Are those specific genetic mutations identified with ASD?

A. No.

Q. Same question for ADHD.

And can we agree, autism spectrum disorder is going -- we're going to refer to it as ASD, and attention/hyperactivity deficit -- attention-deficit disorder we'll refer to as ADHD?

A. Yes.

Q. Okay.

A. That would be great.

Q. And with re -- are there specific -- with regard to the signature that you just mentioned, are those specific genetic mutations identified with ADHD?

MS. HUNT: Object to form.

You can answer.

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THE WITNESS: In the previous research that I have worked on where we've looked at transcriptional profiles associated with these exposures, excuse me, we haven't necessarily looked for ADHD-relevant gene expression signatures. We've largely focused on ASD signatures.

QUESTIONS BY MR. PADGETT:

Q. Any other unpublished research or data that you've -- that you're aware of that supports a biochemical mechanism tying acetaminophen to ASD or ADHD?

MS. HUNT: Object to form.

And, Bill, I apologize in advance, but to the extent this gets into anything currently in peer review, Dr. Pearson is not going to be able to answer.

MR. PADGETT: Understood.

THE WITNESS: There's nothing else that I can discuss.

QUESTIONS BY MR. PADGETT:

Q. Okay. Dr. Pearson, is it your opinion that any compound that causes a

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change or changes in the developing brain can lead to an increased risk for ASD?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: I want to make sure I understand your question.

You're asking me whether anything that can cause a change in the -- in the developing brain can cause risk for autism or ADHD -- ASD or ADHD?

QUESTIONS BY MR. PADGETT:

Q. Increased risk, yes, correct.

A. I would not -- I would not respond to the affirmative to that. That is not my stance.

Q. Same question with regard to ADHD. Is it your opinion that any compound that causes a change or changes in the developing brain can lead to an increased risk for ADHD?

MS. HUNT: Same objection.

You can answer.

THE WITNESS: Anything that leads to a change in the developing

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brain, any exposure that leads to a change in the developing brain, does not necessarily increase the risk for ADHD or ASD.

However, things that have the potential at translationally relevant doses to disturb brain development have to be looked at with higher scrutiny for the potential effects on any widespread effects.

So even if the effects of that particular compound aren't specific to ADHD or ASD, the -- it -- they can exacerbate effects that are relevant to ASD or ADHD.

In other words, if an individual carries liability for ADHD or ASD, those exposures may tip the balance towards a particular outcome even if the effects of that particular exposure aren't specific to ADHD or ASD risk.

QUESTIONS BY MR. PADGETT:

Q. And if those specific effects aren't specific to ASD or ADHD risk, the

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types of findings that you just described may be a basis for conducting further research to determine a more specific relationship?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: That's not exactly what I was stating in my response, but it's not incompletely true what you just stated.

In other words, I would have to qualify that response by stating that, you know, responses that -- again, physiologically relevant exposures in the brain that affect neurodevelopment, even if those responses aren't specific to ASD or ADHD health outcomes, neurodevelopmental outcomes, again, they can contribute risk for those particular health outcomes in individuals that are exposed within a background of risk in individuals.

QUESTIONS BY MR. PADGETT:

Q. Which --

A. Even if that's not the only

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risk. Sorry.

Q. Which biochemical changes in the embryotic or fetal human brain have been identified by the scientific community as known, accepted mechanisms leading to ASD?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: Could you restate the question, please?

MR. PADGETT: Which -- can you read it back, please?

(Court Reporter read back question.)

THE WITNESS: You know, that can't answer that question the way that you've asked it because that's -- that's calling to a specific, you know -- that's -- you're asking me to identify something that is overprescriptive. In other words, you're asking me to say that there's one or a set of specific biochemical changes that exist, when in reality such conditions such as ASD and ADHD

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are -- involve a plethora of biochemical alterations in the developing brain.

You have to consider that the developing brain is so complicated, and when you have health conditions such as ASD and ADHD, the com -- it's -- let me take a second. It's incredibly heterogeneous from individual to individual.

And as you've had from other experts that have been in this case, every individual is a little bit different. So you can't expect to say that there's one set of biochemical changes that's accepted as the, you know, ASD or ADHD perturbations that define that particular disorder.

There's set of clinical perturbations that are typical to these disorders but not specific to these disorders. So if you were to try to pin me down on one or a set of those, and then an individual actually in reality has different sets of those

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or has something that's independent of those, that's actually accepted to be the case.

But you would try to catch somebody out by saying, like, oh, well, that person didn't actually have this 1 or 2. That's actually an unfair characterization of the biology of these highly complicated and heterogeneous neurodevelopmental disorders.

I don't know how clear I was in that. But what I'm trying to say is that, again, it's highly heterogeneous. You're dealing with the most complicated organ in known existence. Its development is highly complicated.

When you -- when you think about how the disorder comes to be, you're dealing with a perturbation and changes that are tipping the course of the development to an extent to where individuals aren't -- you know, can be highly functional but have alterations

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in their development that you can't just look on a brain scan and see.

But those individuals don't behave completely neurotypically, so you can't just define like a tumor, oh, there's a tumor, and that's what this individual is.

Essentially what you're asking me to do is say, what's the tumor for this individual. It's sort of an unfair question.

QUESTIONS BY MR. PADGETT:

Q. You mentioned a plethora of set of mechanisms.

Can you identify among the -- that plethora those mechanisms, biochemical changes, those -- strike that.

Can you identify among the plethora that you mentioned earlier those specific biochemical changes in the embryonic or fetal human brain that have been identified by the scientific community as known, accepted mechanisms leading to ASD?

MS. HUNT: Object to the form of the question.

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You can answer.

THE WITNESS: So you just asked the same question. For the sake of this deposition, I will go ahead and start listing some.

So there are synaptic changes. There's chromatin alterations. There's columnar defects. There are epigenetic changes. There are growth and guidance factor alterations. There's axonal guidance disruptions. There are -- let me think for a moment -- local hyperconnectivity, large scale, global underconnectivity. I mean, these are things that have been replicated many times in many different studies.

This is for autism, by the way. This is not for ADHD.

These are the types of things that you see many times that are representative of autism. That doesn't mean for every individual that has autism that they have all of those things. These are things that are in

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a bell curve. That's what's typical across autism.

Again, it's highly heterogeneous. It doesn't mean that every individual that has autism has those same white matter defects. That doesn't mean that every individual is going to have that. But those are things that tend to happen. They're synaptic alterations, cell adhesion alterations. These are accepted within the community as things that are common amongst autism.

So when you think about modeling and understanding mechanisms and causality in autism, when you model this preclinically and you expose animals, if you expose them to acetaminophen and then you see these things, then there's no question that there's causality.

QUESTIONS BY MR. PADGETT:

Q. The various list of things that you went through, synaptic changes, epigenetic changes, axonal changes, growth

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factors, those are effects seen in individuals with autism spectrum disorder, correct?

A. Yes.

Q. Has the scientific community identified those as -- those mechanisms as things seen in the fetal brain that lead to autism?

MS. HUNT: Object to the form of the question.

But you can answer.

THE WITNESS: Well, there wouldn't be a method to do an experiment in people to resolve whether it leads to that. You know, so I -- that's an absurd question. I'm sorry.

QUESTIONS BY MR. PADGETT:

Q. Well, my -- let me put it this way.

Has the scientific community identified any of those mechanisms that you've just listed as changes, generally accepted changes, that are seen in the fetal brain that lead to autism?

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MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: I would have to hear that question again. I'm sorry. I apologize.

QUESTIONS BY MR. PADGETT:

Q. Has the scientific community identified any of those mechanisms that you've just -- that you listed as generally accepted changes that occur in the fetal brain that lead to autism?

MS. HUNT: Same objection.

You can answer.

THE WITNESS: These are generally accepted. As leading to autism.

QUESTIONS BY MR. PADGETT:

Q. Changes in the fetal brain?

A. These are seen in the fetal brain as well.

Q. Of humans?

A. Well, again, you can't measure them in the fetal brain and then track out if individuals are going to have autism or not.

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It's not possible to do that.

Q. Okay.

A. It's not possible to answer your question the way it's asked.

Q. Which biochemical changes in the embryonic or fetal human brain have been identified by the scientific community as known, accepted mechanisms leading to ADHD?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: I don't believe I can answer your question.

QUESTIONS BY MR. PADGETT:

Q. You can't -- you can't answer my question because you can't sit -- as you sit here today identify them?

A. I don't think your question is answerable based on logic.

Q. You mentioned, you know, animal studies have -- you know, have shown changes.

Which of those changes have been ident -- in the fetal human brain, which of those changes have been identified by the scientific community as accepted prenatal

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changes that lead to ADHD?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: So you mentioned animals. Are you asking about humans or animals now?
QUESTIONS BY MR. PADGETT:
Q. I'm asking which of the change -- any changes seen in prenatal or, you know, up to PN 10 dosing of chemicals -- of any chemical that have been shown to be mechanisms accepted by the scientific community as leading to ADHD.
A. I'm sorry, I'm really confused now because you were talking about human prenatal, but now you're talking about dosing. I'm not trying to be difficult now. I just really don't understand the question now.
Q. Can you identify any biochemical changes seen in any scientific research, whether human or animal, that have been -- in the fetal brain that have been accepted by the scientific community as leading to ADHD?

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MS. HUNT: Object to the form of the question.
Answer, if you can.
QUESTIONS BY MR. PADGETT:
Q. In humans.
A. I don't know how to answer your question.
Q. Have you -- you know, we talked briefly about Baker 2023.
Have you published any peer-reviewed articles or literature other than Baker 2023 on acetaminophen?
A. I don't believe I have.
(Pearson Exhibit 68 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit 68 and ask you to confirm that's a copy of the Baker 2023 study.
A. It is.
(Pearson Exhibit 69 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Okay. I'm going to hand you

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what's been marked as Exhibit 69 and represent to you this is a portion of a draft of Baker 2023 with comments from a PBL1 and a BBH2R1.
Do you see that?
A. Yes.
Q. And it's -- PEARSON_01872 is the Bates number.
Do you see that?
A. I see that.
Q. Okay. Are you PBL1 there?
A. I am.
Q. Okay. And is Brennan Baker, BBH2R1, the -- and eventually the lead author of Baker 2023?
A. Yes.
Q. And do you see there, the first comment says, quote, "The title needs to be more provacative or at least signal the findings better," end quote.
Do you see that?
A. Yes.
Q. Okay. And you're referring to a previous proposed title of "Effect of acetaminophen exposure during gestation and

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lactation on mouse behavior in frontal cortex gene expression," right?
A. Yes.
Q. Okay. And is this red your proposed new title, "Developmental acetaminophen exposure produces ADHD-like behavioral alterations in mice, paren, in a sex-dependent manner"?
A. That was probably my suggestion, yes.
Q. Okay. And does Mr. Baker have his Ph.D. now?
A. He does, yes.
Q. Okay. We'll call him Dr. Baker.
And Dr. Baker responded to your comment, quote, "I don't think we can say 'ADHD-like.' Can we say 'anxiety'," end quote?
Do you see that?
A. I see that.
Q. Did you and Dr. Baker have any discussion about this particular issue offline, so to speak, about "ADHD-like" being included in the title?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: I don't recall. My assumption is we probably did. And I think I responded within the third title, suggestion of the third title.
QUESTIONS BY MR. PADGETT:
Q. Okay. And the third title is "Sex-specific neurobehavioral and frontal cortex gene expression alterations following developmental acetaminophen exposure in mice," right?
A. Yes.
Q. Was that -- is that where you landed?
A. It's close, yeah.
Q. Okay.
A. It's close to where we landed, yeah.
Q. And the -- so the "ADHD-like" language that you proposed is not included in the title of the published study, right?
A. It was not included, yes.
Q. Did Dr. Baker feel that the findings of the 20 -- Baker 2023 study did

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not support using "ADHD-like" in the title?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: You would have to ask Dr. Baker himself. I don't -- I don't want to put words in his mouth.
QUESTIONS BY MR. PADGETT:
Q. You don't specifically recall whether in your conversations offline, so to speak, he indicated that?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: I don't remember if we discussed this any further.
QUESTIONS BY MR. PADGETT:
Q. And I've looked at some of the other background materials related -- leading up to the submission of Baker 2023 for publication.
At the outset, Dr. Baker's proposed research project was focused on ADHD, right?
MS. HUNT: Object to the form of the question, including the prefatory statement.

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You can answer.
THE WITNESS: Dr. Baker was interested in understanding -- using a mouse model to understand ADHD-like effects of acetaminophen, yes.
QUESTIONS BY MR. PADGETT:
Q. And that was the impetus for the study that you -- that Dr. Baker and the rest of the team, including you, put together, right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: We were interested in all of neurodevelopmental effects, not just ADHD, but ADHD was a central focus.
QUESTIONS BY MR. PADGETT:
Q. Okay.
A. Yeah.
Q. Baker 2023 showed a lack of hyperactivity in treated animals, right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Well, there was a change in local motor activity. There

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was less activity in males.
QUESTIONS BY MR. PADGETT:
Q. So it was the -- it was hypoactivity, the opposite of hyperactivity, correct?
A. Hypoactivity.
Q. Okay. So it showed a lack of hyperactivity in treated animals, correct?
A. There was a disruption in activity.
Q. That's not my question.
Baker 2023 showed a lack of hyperactivity in treated animals, right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: There was, strictly speaking, a lack of hyperactivity.
QUESTIONS BY MR. PADGETT:
Q. If you could turn to page 9 of Baker 2023. In the paragraph, the first full paragraph, first sentence, it says right there that the results demonstrate a lack of hyperactivity, right?
A. Yeah, but it does not preclude

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ADHD relevance.
Q. Okay. And I guess later in that paragraph there's a reference to spontaneously hyperactive rats, SHR rats --
A. Yes.
Q. -- show ac -- show hyperactivity, impulsivity and inattention in other tests, even though there was one study that showed them being less active in an open field test; is that right?
A. Yes. It says they're less active than the Wistar Kyoto rats in the running wheel and less active in Sprague Dawley rats in open field tests.
Q. Baker 2023 is a mouse study, right?
A. It is a mouse study.
Q. And with regard to hyperactivity, impulsivity and inattention, there was no finding consistent with those three behavioral traits for ADHD in Baker 2023, correct?
MS. HUNT: Object to the form of the question.
You can answer.

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THE WITNESS: You're asking whether Baker 2023 had findings with respect to impulsivity, inattentiveness and hyperactivity?
QUESTIONS BY MR. PADGETT:
Q. Yes. Consistent with ADHD.
A. Well, animal models don't have to have directional concordance to be relevant, as I state clearly in my expert report. That's a -- that's misconstruing the animal model literature.
Q. I've already discussed hyperactivity.
Was there any assay test in Baker 2023 in which the findings were consistent with the animal model for ADHD for impulsivity?
A. We didn't look directly at impulsivity. We looked at attention and focused on attention, not impulsivity.
Q. Was there any assay or test in Baker 2023 that showed a finding consistent with the ADHD animal model for -- with regard to attention?
MS. HUNT: Object to the form

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of the question.
You can answer.
THE WITNESS: Well, we -- if you look at the five-choice data, even though it was not statistically significant, we only had it in a four per sex, we saw biologically potentially meaningful differences in omission data, for instance.
So in panel B on Figure 6, males had higher omissions in the variable delay probe. So, for instance, Figure 6B on the third column, males had more omissions in the premature responses. They had more premature responses, which actually indicates maybe they had more impulsivity.
So there's maybe some suggestions that there's some inattentiveness and some impulsivity, but we were a bit underpowered. But this was a limitation in the number of Bussey chambers, which are the operative chambers that we have access

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to.
So unfortunately, in the Baker 2023 paper, we just don't have enough data for the attentional and impulsivity types of measures, so more data are needed to actually say anything about attention and impulsivity.
QUESTIONS BY MR. PADGETT:
Q. So you're unable -- strike that.
A. There might -- but there still can be meaningful pilot information that could be drawn from this study, regardless. But we were conservative about the conclusions we were trying to draw from it because it's not very statistically powered to try to draw any conclusions.
Q. Can you go to the top -- the bottom of page 9, please?
A. Sure.
Q. And it goes -- there's a sentence that goes over to page 11, because there's a chart there.
The study article specifically

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states that developmental APAP -- and can we agree that APAP is the same as acetaminophen?
A. Yes.
Q. "Developmental APAP exposure was not associated with mouse attention deficits in the five-choice serial-reaction task test."
A. I'm not seeing what you're seeing, but I'm sure that's what we say here.
Q. It's at the top of page 11.
A. Okay. Yes.
Q. And then you recall, I think from -- I believe it was Exhibit 69, Dr. Baker asks whether anxiety could be used in the title.
With regard to anxiety, that's discussed in the conclusion of the article. Can you turn to that, please?
First, I have a couple of questions about anxiety. And if you want to refer to your report, you can.
But at pages 22 to 23 and 27 of your amended report, there's a discussion about the DSM-5 and neurodevelopmental disorders, including specifically with regard

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to ASD and ADHD.
Do you recall that?
A. I'd like to get there.
You said 22?
Q. Yes. And 27 to 28.
A. Okay.
Q. Do you -- do the DSM-5 criteria for ASD include anxiety?
MS. HUNT: Object to form.
And, Counsel, I'll let this go, but if we're going to go deep into the DSM criteria, I'd ask that he have a copy.
MR. PADGETT: He discusses it in detail in his report.
MS. HUNT: That's fine. But if you're asking him about a specific diagnostic criteria in detail, I'd ask that he have a copy. At this level, it's fine.
THE WITNESS: I don't believe anxiety is a diagnostic criteria, but anxiety is a large component of autism.

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QUESTIONS BY MR. PADGETT:
Q. Anxiety is a symptom of numerous varied neurodevelopmental disorders. Agree?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: It may be, but not necessarily.
QUESTIONS BY MR. PADGETT:
Q. Do the DSM -- do you know whether the DSM criteria for ADHD includes anxiety?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I would have to see the DSM criteria.
QUESTIONS BY MR. PADGETT:
Q. Okay. Did you look at the DSM criteria when you were putting your report together?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: No, I didn't look at them in detail.

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QUESTIONS BY MR. PADGETT:
Q. Okay. So are you aware whether the only neurodevelopmental disorder that includes anxiety in its diagnostic criteria set forth in the DSM-5 is child -- childhood-onset fluency disorder, also known as stuttering?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: That's outside of the purview of my mandate for this proceedings.
QUESTIONS BY MR. PADGETT:
Q. So you --
A. I -- that's not something I have expertise in.
Q. So you don't know; is that right?
A. That's not -- that's not something that's part of my expertise, is that particular disorder, so...
MS. HUNT: Counsel, if we're going to do a pop quiz on the DSM, I would ask that you bring a copy so we can look at it together.

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MR. PADGETT: He just said it wasn't part of his purview.
QUESTIONS BY MR. PADGETT:
Q. But my question is, so you don't -- my -- is, so you don't know whether or not stuttering is the only neurodevelopmental disorder that has anxiety in the DSM-5 criteria? That's my question.
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Yeah, again, I'm not a clinician. I know a large amount about anxiety and how to measure it in animals. If you'd like to ask me about that, I'd love to tell you about that.
But this is -- the DSM -- this is background information that was intended to provide background and to help the reader orient.
QUESTIONS BY MR. PADGETT:
Q. It's -- similar question.
As you sit here today, do you know whether or not stuttering is the only neurodevelopmental disorder that includes

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anxiety in its diagnostic criteria set forth in the DSM-5?
MS. HUNT: Objection. Asked and answered multiple times.
You can answer again.
THE WITNESS: That is not something I know about, no.
MS. HUNT: Counsel, we've been going a little over an hour. Is this a good time for a break?
MR. PADGETT: Sure.
VIDEOGRAPHER: The time right now is 9:48 a.m., and we're off the record.
(Off the record at 9:48 a.m.)
VIDEOGRAPHER: The time right now is 10:03 a.m., and we're back on the record.
QUESTIONS BY MR. PADGETT:
Q. Back from a little break, Dr. Pearson. Just a couple quick follow-up questions on the Baker 2023 study.
If you could turn to page 11, it's right before that last paragraph of the article.

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You indicate there that the open field and pup ultrasonic vocalizations tests indicated elevated anxiety in male offspring exposed to -- developmentally to APAP.
First of all, with regard to pup ultrasonic vocalizations, you're talking about the change seen with regard to decreased -- sorry, increased vocalizations, right?
A. Yes.
Q. And with regard to -- was there any -- I don't -- I didn't see it. Was there anything in the study discussing that these USVs, the ultrasonic vocalizations, were unusual?
A. In this paper we discuss the vocalizations in the sense that they're -- there's sex differences in the presentation of them and the fact that the pattern of them are aberrant based on the prenatal exposure to the medication.
Q. So they're increased, and how were they aberrant?
A. So in that the males are

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exhibiting more relative to the controls. That exposed males are exhibiting more vocalizations relative to the unexposed males.
Q. So when you say "aberrant," that's the same as more, or increased, right?
A. Increased or decreased would be aberrant.
Q. Okay. And with regard to the open field test, are you -- the only thing that I saw statistically significant was the decreased total ambulatory movement for the males as reflected in Figure 2.
Is that right?
A. I'm going to Figure 2.
Q. At least following a Bonferroni correction, right?
A. I'm sorry, could you say that again?
Q. The only -- the only finding that was statistically significant with regard to the open field testing following Bonferroni correction was the total ambulatory movement as reflected in Figure 2 on page 4, correct?

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MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: That's not correct.
So the ambulatory movements were statistically different, the rearings were different, and the center durations were different based on treatment.
QUESTIONS BY MR. PADGETT:
Q. My question was following Bonferroni.
A. Bonferroni?
Q. Bonferroni. Correction.
The plus sign is for Bonferroni correction statistical significance, and the asterisk is following Bonferroni correction, correct?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: That's not entirely correct. So I believe you're looking at Figure 2B?

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QUESTIONS BY MR. PADGETT:
Q. Yes.
A. That's for the sex stratified analysis?
Q. Okay. Let me put it -- let me ask it this way.
The open field test finding of anxiety was based on the finding of decreased total ambulation and decreased rearings in the male mice as reflected in Figure 2, correct?
A. That is the main finding in the open field test, but the open field test is not just measuring anxiety. In fact, that's not the main finding of the open field. That's locomotor -- locomotor behavior.
But you can also evaluate risk assessment behavior, thigmotaxis behavior and other behavioral paradigms, other behavioral parameters, in the open field test.
Q. All right. And the main -- when you say the main focus of the -- as it relates to testing for ADHD, the main focus of the open field test is that you're looking for increased ambulation in the treated

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animals, or increased rearings in the treated animals, that would be consistent with the ADHD model, correct?
MS. HUNT: Objection to form.
THE WITNESS: That is not correct. Sorry. Apologies. That is not correct.
We're not looking for disturbances in these behavioral paradigms. Directionality is not required. We're looking for perturbations in these behavioral readouts. Increases in these behaviors that are statistically significant, decreases in these behaviors that are statistically significant can still be relevant for ADHD-like behaviors.
We're not measuring ADHD in these animals. They are animals, not people.
QUESTIONS BY MR. PADGETT:
Q. And then with regard to anxiety, do you see where it says, second, the open -- after you discussed the open

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field and USV tests, there was no effect in the elevated plus maze, which is a common assay for anxiety-related behavior, right?
A. You're on page 11?
Q. Yes.
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: So if you're asking me whether there were changes in the elevated plus maze -- is that your question?
QUESTIONS BY MR. PADGETT:
Q. Yes.
A. There were not changes in the elevated plus maze. Statistically significant changes in the elevated plus maze.
Q. And as you state there, that -- that is a common assay for anxiety-related behavior, right?
A. It is a common rodent test for anxiety-related behavior.
Q. So to the extent the conclusion is that open field and pup ultrasonic were

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consistent with anxiety, the elevated plus maze was not consistent with increased anxiety --

MS. HUNT: Object to the --

QUESTIONS BY MR. PADGETT:

Q. -- correct?

MS. HUNT: Sorry. Object to the form of the question.

You can answer.

THE WITNESS: As I stated previously, the open field test that was run with these mice, the main intention of this test was to look at local motor behavior. But the task can also be used to look at mood and anxiety-relevant behaviors as well. Not mood. Anxiety-related behaviors as well. Risk assessment-related behaviors.

QUESTIONS BY MR. PADGETT:

Q. In your report, it looks like pages 39 to 46, in the second half of that section you discuss the ADHD model for -- ADHD animal model, right? And various assays used for it?

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A. In my -- in my report, I discuss behavioral paradigms and outcome variables that could be used to assess outcomes that can be relevant for neurodevelopmental outcomes such as ADHD and ASD-relevant effects.

Q. And, you know, in terms of the expected results consistent with the animal model for ADHD, that increased ambulation and increased rearings is what would be expected for consistency with the ADHD animal model, correct?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: That is not in line with the testimony that I've given.

QUESTIONS BY MR. PADGETT:

Q. Okay. If that's what it says in your report -- well, let me ask you this.

Have you -- you haven't amended that section describing the animal model assays for ASD and ADHD since your June 28 -- sorry, June 21 amended report, right?

MS. HUNT: Object to form.

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You can answer.

THE WITNESS: Are you asking me whether I've amended that section where I discuss the behavioral paradigms?

QUESTIONS BY MR. PADGETT:

Q. Yes.

A. No, that's not been amended.

Q. Okay.

A. So the behavioral readouts that have been provided here are examples of behavioral paradigms. Any directionality of discussion that's given here are provided as examples. They're not provided as the only types of readouts that are required to have relevance for these behavioral readouts.

This is background information that's provided as examples. This is not meant to be comprehensive or the litmus test for what's -- the only -- it's not prescriptive as to what's required for the outcomes for neurodevelopmental relevance.

Q. We discussed unpublished research earlier, and there was some such unpublished research that you indicated you

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could not talk about because it was currently in peer review.

Do you recall that discussion?

A. I recall that discussion.

Q. Okay. Are you relying on any data or research that is currently in peer review for your opinions in this case?

A. No.

Q. Do you anticipate providing a supplemental report regarding that unpublished research?

MS. HUNT: Objection.

You can answer.

THE WITNESS: As it states in my report, I say that I'm open to any new information that comes to light, but my report is based solely on published information -- published, publicly accessible information in forming my opinion and the weight of evidence.

QUESTIONS BY MR. PADGETT:

Q. I mean, the unpublished data that has been submitted for peer review, do you have an anticipated date on when you will

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learn of whether it's been accepted for publication?
MS. HUNT: Objection.
Answer, if you can.
THE WITNESS: I do not have -- I can't refer to anything specifically and answer that question.
QUESTIONS BY MR. PADGETT:
Q. Are you part of any peer review group for any unpublished data or research relating to a study on acetaminophen and neurodevelopmental disorders?
MS. HUNT: Objection.
Answer, if you can.
THE WITNESS: I can't answer that.
QUESTIONS BY MR. PADGETT:
Q. Not even whether you are?
A. It's -- it would not be proper for me to answer that question.
Q. So when the unpublished research was submitted for peer review, did you disclose to whatever journal or journals involved that you are doing -- you're being paid by plaintiffs' counsel for this

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litigation?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: So I'm just going to go ahead and give some clarification and go on the record by saying I'm not indicating that I've submitted anything, and I'm not indicating that I'm peer reviewing anything here. So we should just dispense with any discussion of any of this.
If I were peer reviewing anything, I'm not -- by the rules of the journal, I'm not allowed to discuss that. So it would not be proper for a continued discussion of that.
And if I myself have data that I'm submitting for publication, that's the purview of my own research in my own lab.
But again, if there's stuff that's peer -- that I'm peer reviewing, I'm not allowed to discuss

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that as per the rules of the journal.
QUESTIONS BY MR. PADGETT:
Q. Let's go outside anything specific.
If you were to submit in six months a study for -- a study article for publication involving acetaminophen and possible neurodevelopmental effects, would you disclose to the journal that you're submitting it to that you were being paid by the plaintiffs' counsel in this case?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I would not need to disclose that because I do not receive funding for my research. The only things I would need to disclose are my funding sources. So I'm not conflicted.
Now, if somebody would like to give me a research for my -- give me funding for my research, then I would disclose that.

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QUESTIONS BY MR. PADGETT:
Q. I think your report reflects this, but did you look at documents produced by the FDA in producing -- preparing your report?
A. I did.
Q. Okay. And those documents are as recent as 2022, right?
A. I do -- I do not recall the recency of those documents, the date of the recency of those documents, off the top of my head.
Q. Okay. In any event, the conclusion that the FDA has reached with regard to any developmental neurotoxicity of therapeutic doses of acetaminophen is not in agreement with your opinions here, correct?
MS. HUNT: Objection. Misstates evidence.
You can answer.
THE WITNESS: I've seen opinions within FDA production that individuals -- that the opinions are mixed within the FDA, so I don't necessarily agree with that statement.

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QUESTIONS BY MR. PADGETT:
Q. Well, let me ask you this.
The FDA has not come up -- come out with an FDA conclusion, publicly or privately, as far as you know, based on the documents reviewed, that are in agreement with your conclusions in this case, agree?
MS. HUNT: Object to the form of the question.
Answer, if you can.
THE WITNESS: To my knowledge, the FDA hasn't seen my opinion, so how would they be able to opine on my conclusions?
QUESTIONS BY MR. PADGETT:
Q. I'm not asking whether they've seen it. I'm asking whether the FDA has come out, either publicly or privately, with a conclusion on behalf of the FDA that is consistent with your opinions in this case.
MS. HUNT: Same objection.
You can answer.
THE WITNESS: My understanding is that the FDA is continuing to evaluate information as it comes.

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QUESTIONS BY MR. PADGETT:
Q. Have you seen any such FDA -- any such conclusion on behalf of the FDA that is consistent with your opinions in this case?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I haven't seen an opinion from the FDA that is in contradistinction to my opinion or supports my opinion.
QUESTIONS BY MR. PADGETT:
Q. Have you ever asked to serve on any decision-making committee regarding drug safety?
Have you ever been asked to serve on any decision-making committee regarding drug safety?
A. Not to my recollection, no.
Q. Have you ever been asked to serve on any decision-making committee regarding women's health?
MS. HUNT: Object to form.
You can answer.

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THE WITNESS: Any safety committee regarding women's health? I do not believe I have.
QUESTIONS BY MR. PADGETT:
Q. As we're sitting here today, August 2023, the American College of Obstetricians and Gynecologists disagrees with your general causation opinion that acetaminophen is a developmental neurotoxicant capable of causing ASD, correct?
A. My understanding is that the ACOG has released their statement that -- to that -- to that regard, yes. But I don't think that every single member of ACOG is necessarily in agreement with that.
Q. And the same is true for the Society for Maternal-Fetal Medicine. As of today, the Society for Maternal-Fetal Medicine does not agree with your opinion -- with your general causation opinion that acetaminophen is a developmental neurotoxicant capable of causing ASD, correct?
MS. HUNT: Object to form.

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You can answer.
THE WITNESS: Similar to the FDA, I don't think they've been able to see my report, but I've seen allusions to the -- to that regard, yes.
QUESTIONS BY MR. PADGETT:
Q. And same questions with regard to ACOG and Society for Maternal-Fetal Medicine.
As of today, those organizations do not agree with you with regard to your general causation opinion that acetaminophen is a developmental neurotoxicant capable of causing ADHD, correct?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: I would give the same answer as before.
QUESTIONS BY MR. PADGETT:
Q. Okay. Are you aware of any medical organizations in the United States that as of today agree with your general causation opinion here?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: I haven't inventoried all the medical organizations to see what their opinions are with respect to this topic, so it would be difficult for me to answer that.
QUESTIONS BY MR. PADGETT:
Q. Well, I'm just asking you, as you sit here today, are you aware of any that agree with your general causation opinion in this case?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: And I understand from the Bauer consensus statement that there's a lot of individuals that are medical practitioners that have a similar viewpoint.
QUESTIONS BY MR. PADGETT:
Q. Are the signers of the Bauer 2021 consensus statement a medical organization collectively?
A. I don't know.

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Q. Do you have a draft of an additional expert report that you're working on now, or anything like that?
MS. HUNT: Object to the form of the question.
Answer, if you can.
THE WITNESS: I don't believe I have another draft of an expert report.
QUESTIONS BY MR. PADGETT:
Q. Okay. So as of today, we have in writing whatever your opinions are in this case, correct?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: My opinion -- my expert report is subject to change based on new information, as it says in my expert report.
QUESTIONS BY MR. PADGETT:
Q. But as of today, your opinions are set forth in your expert report -- reports, plural?
A. That is a fair statement.
(Pearson Exhibit 70 marked for identification.)

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QUESTIONS BY MR. PADGETT:
Q. Okay. I'm going to hand you what's been marked as Exhibit 70.
Can you identify this Exhibit 70 for me?
A. Yes, this is a -- this is an e-mail chain.
Q. And there's an e-mail -- and one of them -- this e-mail is from you, at least the December 18, 2022, 11:21 a.m. There's an e-mail from you to fellow coauthors on the Baker 2023 study, right?
A. Yes.
Q. And it's Dr. Brennan -- sorry. Dr. Baker, Dr. Hamblin and Dr. Yang, right?
A. Yes.
Q. And there you note that Baker 2023 has been accepted for publication, correct?
A. Yes.
Q. Okay. And then you state, quote, "We are pissing off Johnson & Johnson and all obstetricians simultaneously. I'd say that's impactful," period, end quote.

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Correct?
A. Yes.
Q. Okay. At this time, you had been engaged by plaintiffs' counsel -- strike that.
At this time, you had at least been contacted by plaintiffs' counsel for this litigation nine months earlier, based on your prior testimony?
A. That sounds about right.
Q. Okay. Was one of your research team's goals in conducting this study to make an impact by, quote, pissing off, end quote, Johnson & Johnson?
A. No, that would not have been the goal.
Q. Why did you say this then as to Johnson & Johnson specifically?
A. Well, this statement just reflects the sort of frustration at sort of the inaction and controversy and skepticism about the preclinical literature and the observational epi literature, and the fact that many of us scientists have been working on this topic, and the fact that there's just

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inaction and continued skepticism.
And so working on this and working on this, and the fact that we talk about this topic and it's met with disdain or met with, again, to use the same term over and over again, skepticism, finally getting this paper accepted elicited this response, which was a bit tongue in cheek.
Q. And as we -- strike that.
And was one of your research team's goals in conducting the study to make an impact by, quote, "pissing off...all obstetricians," end quote?
A. No.
Q. Did you or any others on your research team follow up to see the extent of it -- of any impact paid by pissing off Johnson & Johnson?
A. We did not follow up on that, no.
Q. Did you or any your research team follow up to see the extent of any impact made by, quote, "pissing off," end quote, all obstetricians?
A. No.

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Q. Why did you find it impactful to piss off all obstetricians?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: Can you restate that question? I'm sorry.
QUESTIONS BY MR. PADGETT:
Q. Why did you find it impactful to piss off all obstetricians, as you put it here?
A. We didn't. Again, as I said, this -- this statement just reflected our excitement about finally getting our paper published and being able to provide more support for what we believe to be an important topic.
Q. So are you now retracting that you'd say that this study was impactful?
MS. HUNT: Object to --
QUESTIONS BY MR. PADGETT:
Q. In pissing off J&J and all obstetricians simultaneously?
MS. HUNT: Object to the form of the question. Misstates testimony.

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Dr. Pearson, you can answer.
THE WITNESS: If you're asking me whether I think the impact of the study is that it frustrates the corporate entity and it frustrates clinicians, that's not what we believe the impact of the study actually is.
We believe the impact of the study is by providing more and strong evidence that the medication is a neurodevelopmental toxicant that can contribute to these health outcomes.
We think that it does challenge this view that the corporate entity and the clinicians have, and that is important to us.
QUESTIONS BY MR. PADGETT:
Q. Do you believe it's inappropriate for an OB/GYN or a maternal-fetal medicine physician to consider treatment of fever and pain in pregnant women an important issue?
MS. HUNT: Object to the form of the question.
You can answer.

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THE WITNESS: Can you repeat the question?
QUESTIONS BY MR. PADGETT:
Q. Do you believe it's inappropriate for an OB/GYN or a physician or a maternal-fetal medicine physician to consider treatment of fever and/or pain in pregnant women an important issue?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: I do -- I do not think that a maternal-fetal medicine doctor or obstetrician should not consider that an important issue. They should consider that an important issue.
I would never argue the alternative.
QUESTIONS BY MR. PADGETT:
Q. And if you want to refer to your report, you can.
In your summary of the study on page 113 of your report, you note that a single dose of 150 milligram per kilogram per day was used, and you state that was at the

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high end of dosing, correct?
A. You say on 113 on the report?
Q. Yes.
MS. HUNT: I'm sorry, can you specify the study we're talking about?
MR. PADGETT: We're talking -- sorry. We're talking about Baker 2023.
MS. HUNT: Thank you.
THE WITNESS: Which paragraph?
QUESTIONS BY MR. PADGETT:
Q. Strike that.
If you could turn to Baker 2023, it's exhibit...
Which exhibit is that?
Apologies.
A. 68.
Q. 68.
Turn to page 2, please.
A. (Witness complies.)
Q. And there on the right common -- or column, you state that "the dose of 150 milligrams per kilogram per day is within the range of human exposure accounting for allometric scaling and has previously

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been shown to result in the highest serum concentrations of APAP without inducing liver toxicity in mice."
Correct?
A. That's what it states.
Q. Okay. Sorry. Can you turn back to page 113 of your report?
A. I'm there.
Q. Yeah.
Right after -- it's about the fourth or fifth sentence there in your summary for Baker 2023. You state that you opted to be at the high end of dosing to see if an effect existed, right?
A. That's what it states.
Q. Okay. And so this is -- 150 milligrams per kilogram per day is not just at the high end of dosing, but Baker 2023 confirms that doses above 100 milligrams per kilogram per day can induce liver toxicity, right?
A. Baker, et al., does not say that.
Q. At what levels have liver toxicity been shown in mice?

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MS. HUNT: Objection.
QUESTIONS BY MR. PADGETT:
Q. With acetaminophen.
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: There's -- that's a massive literature, so you might have to narrow a bit.
QUESTIONS BY MR. PADGETT:
Q. Has a 150 milligrams per kilogram dose been shown to cause liver toxicity in mice?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: It would depend on your definition of liver toxicity.
If your measure is AS -- an AST elevation, an ALT elevation, liver necrosis, liver failure -- I mean, if you're referring to a specific study, I'd be happy to look at it.
But generally 100 milligrams per kilogram does not cause liver

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toxicity in mice.
QUESTIONS BY MR. PADGETT:
Q. But 150 milligrams per kilogram?
A. Generally, no.
Q. Okay. Has 150 milligrams per kilogram been shown in published literature to show liver toxicity in mice?
A. I would repeat my response from before. It depends on your definition of liver toxicity.
Q. Did you review Dr. Cabrera's report in this case?
A. I did.
Q. It was previously marked as Exhibit 12 in this litigation. I'll hand it to you, if you want to have it handy.
But I'm referring to page 34.
MS. HUNT: Do you have an extra copy, Counsel?
MR. PADGETT: Oh --
MS. KAPKE: We don't. I'm sorry.
MR. PADGETT: We don't. I'm sorry.

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MS. KAPKE: It's the Cabrera report.
MS. HUNT: Okay. In the future, I'd just --
MR. PADGETT: Yeah.
MS. HUNT: -- ask for the courtesy of having a copy for me, please.
QUESTIONS BY MR. PADGETT:
Q. Dr. Cabrera put the mouse single therapeutic dose, and it's in bold on page 34 there, at 150 to 200 milligrams per kilogram, as reported from experimental studies and calculated using human equivalent conversions, right?
A. In bold it states, "Based on these data and calculations, a mouse dose of approximately 150 to 200 milligrams per kilogram." And then it goes on.
Q. Would be in the therapeutic --
A. In the therapeutic range.
Q. Okay. And he also states that a rat single therapeutic dose would be at 100 to 150 milligrams per kilogram, as reported from experimental studies and calculated

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using AGD conversions, correct?
A. That's what I read.
Q. Okay. So the human -- do you agree that human equivalent therapeutic dose in mice is there's -- is therefore somewhere below 150 milligrams per kilogram per day?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: You're asking whether I think it's below this?
QUESTIONS BY MR. PADGETT:
Q. Below 150 milligrams per kilograms per day for mice.
A. I don't --
MS. HUNT: Same objection.
THE WITNESS: -- necessarily agree with that, no.
QUESTIONS BY MR. PADGETT:
Q. Strike that. Strike that.
Would you agree that the human equivalent single therapeutic dose in mice is somewhere below 150 milligrams per kilogram?
MS. HUNT: Object to the form of the question.
Answer, if you understand it.

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THE WITNESS: No, I think that's a -- I don't think you can narrow it to a single point like that. It depends on the study. It depends on the route of administration. It depends on the application. It depends on if you're looking for fever reduction. It depends on if you're looking for pain. It depends on if you're doing toxicity. Amongst other things.
QUESTIONS BY MR. PADGETT:
Q. And I'm talking about the human equivalent therapeutic dose in mice.
Would you a -- as in per the label, would you agree that it is somewhere below 150 milligrams per kilogram for a single dose?
MS. HUNT: Objection. Form.
Dr. Pearson, you can answer.
THE WITNESS: Well, this is Dr. Cabrera's report. Dr. Cabrera is saying it's between 100 -- approximately 150 to 200 milligrams per kilogram.

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I don't have any strong reason to disagree with Dr. Cabrera.
QUESTIONS BY MR. PADGETT:
Q. Okay.
A. So in that sense, I would not agree with you.
Q. Would you agree that a human equivalent therapeutic dose in mice, using Dr. Cabrera's numbers, would be below 200 milligrams per kilogram for a single dose?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I would concur with Dr. Cabrera, which is approximately 150 to 200 milligrams per kilogram as a human equivalent dose, as stated in his report.
QUESTIONS BY MR. PADGETT:
Q. Therapeutic dose, right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: No. He's saying is therapeutic, not therapeutic dose.

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QUESTIONS BY MR. PADGETT:
Q. Okay.
A. He's saying what is therapeutic. He's not saying a therapeutic dose.
Q. Did you exclude --
A. There's a difference.
Q. Sorry.
Did you exclude studies from your report that administer a dose above 200 milligrams per kilogram in mice or rats?
MS. HUNT: Object to form.
QUESTIONS BY MR. PADGETT:
Q. In your weight of evidence analysis.
A. In my weight of evidence analysis, I certainly excluded studies that were not just above 200, but well above 200 I excluded.
Q. Beck -- the Beck study was including your weight of analysis, correct?
A. I included that, yes.
Q. Okay. And that was -- that involved doses at 250 milligrams per kilogram and 500 milligrams per kilogram, correct?

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A. It was, I believe, zero, 250 and 500, if I remember correctly. I can look.
Q. And --
A. 125 as well.
Q. But it did include 250 and 500 milligrams per kilogram single dose?
A. Zero, 125, 250, 500.
Q. Okay. And Rigobello, among its dosing -- doses included 350 milligrams per kilogram, correct?
A. I would have to look.
Q. Sure. It's in your...
A. Rigobello was mouse.
Q. You have a chart on mouse -- mice.
A. Yeah, I'm looking for that right now.
Q. Rigobello was rat.
A. Rigobello was rat?
Q. Yes. Page 83 of your report.
A. Yeah, so that was zero, 35 and 350.
Q. So you included Rigobello in your weight of evidence analysis even though

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it was -- included a dose of 350 milligrams per kilogram single dose, right?
A. I included Rigobello.
Q. Okay. Are your opinions in this case not limited to answering the question of whether exposure to therapeutic doses in humans of acetaminophen in utero can cause ASD or ADHD?
A. The specific language I used in my report was whether reasonable doses of acetaminophen contribute to neurodevelopmental disorders such as ASD-like and ADHD-like outcomes in rodent models and in vitro models.
Q. Can you turn to page 4 of your report?
A. (Witness complies.)
Q. Under mandate there --
A. Yes.
Q. -- you state, quote, "My expert report addresses whether there is a biologically plausible explanation for the increased risk of neurodevelopmental disorders ASD and ADHD in offspring with prenatal use of APAP, and whether the

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preclinical literature supports that therapeutic, clinical and translationally relevant preclinical doses of APAP show evidence of harm to the central nervous system, particularly to the developing mammalian brain."
Did I read that right?
A. Yeah. And in parentheses, "They were translationally relevant."
"What is translationally relevant are rodent doses that are well below those causing acute liver failure, and particularly the doses that are analgesic or antipyretic in that species and lower."
Q. So regardless of whether it was equivalent of a therapeutic human dose, if it was below doses causing acute liver failure in a rodent, you included it?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: And it states here it's translationally relevant.
QUESTIONS BY MR. PADGETT:
Q. If you could turn to page 2,

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left column, middle of the first column of Baker 2023.
A. Middle of the left column?
Q. Yes.
A. Okay.
Q. It states -- do you see the sentence that starts "Finally"? About the middle of the first full paragraph.
A. Middle of the first full paragraph. I'm having trouble finding that.
MS. HUNT: I am, too.
QUESTIONS BY MR. PADGETT:
Q. Page 2, left column, first paragraph, middle of that paragraph. It starts with "Finally, the mechanisms."
A. Is it -- can you tell me...
Q. It's right before Philippot 2018.
MS. HUNT: Oh.
THE WITNESS: Oh, I see it.
QUESTIONS BY MR. PADGETT:
Q. Okay.
A. I've got it. "Finally, the mechanisms linking." Okay.
Q. There you state, quote,

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"Finally, the mechanisms linking APAP exposure to abnormal neurodevelopment are unclear," period, end quote.
Do you still agree with that statement?
A. In part. But what the statement is indicating is that we don't know everything. Just because we don't know everything doesn't mean we know anything.
So when we write in science, when we're writing a grant proposal, when we're writing a paper, we have to be very conservative in how we write. We have to say that, you know, we don't know everything, therefore, we need to learn more. And that's almost always the case.
Q. What studies have been published this year that now make clear -- that now make the mechanism linking APAP exposure to abnormal neurodevelopment, quote, clear, end quote?
A. A lot of the studies are making things clearer. In 2021, 2022, 2023, there's a lot that's been published. In vitro studies, in vivo studies, more epi, more

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biomarker studies.
Q. I'm talking since publication of Baker 2023.
A. Klein, Xie, that's stuff that --
Q. Okay.
A. -- that -- the rate that the studies are coming out, it's compounding.
Q. And Klein 2023 included dosing at 350 milligrams per kilogram --
A. Yes.
Q. -- which is more than twice the high end of the dosing referred to in Baker 2023 of 150 milligrams per kilogram, correct?
MS. HUNT: Object to the form of the question, as it relates to the wrong species.
You can answer.
MR. PADGETT: Object to form only.
MS. HUNT: Okay.
THE WITNESS: So 350 milligrams per kilogram can be appropriate if you apply allometric scaling.
Rodents are not humans. Rats

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and mice have heartbeats that are 500 times -- 500 beats per minute. They consume oxygen at rates that are much, much higher than humans.
You can't do direct dosing conversions between rodents and humans. That's not appropriate.
QUESTIONS BY MR. PADGETT:
Q. But that's 150 milligrams per kilogram higher than the high end of Dr. Cabrera's therapeutic dose range of 150 to 200 milligrams per kilograms for a single dose, right?
MS. HUNT: Same objection.
You can answer.
THE WITNESS: The Klein, et al., study used allometric scaling in their dose justification as well.
There's various approaches to allometric scaling. There's not one -- there's not a single allometric scaling approach.
QUESTIONS BY MR. PADGETT:
Q. It's 150 milligrams per kilograms higher, though, than the range

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provided by Dr. Cabrera for rats for therapeutic allometric dosing per a single dose pursuant to his HE -- human equivalent dose analysis. Agree?

A. The --

MS. HUNT: Objection. Form. You can answer.

THE WITNESS: Klein and colleagues aren't relying on Dr. Cabrera's expertise in deciding on their dosing. They get to decide that on their own.

QUESTIONS BY MR. PADGETT:

Q. You reference -- you discuss in Baker 2023 the upregulation of estrogen response in females. This is on page 7, bottom right.

Did you or your team do any analysis to determine if these changes seen were adverse or adaptive?

A. If they were adverse or adaptive. We did not have the funding to follow up on those pathways.

Q. Did you do any analysis to determine if these changes were transient or

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permanent?

A. We know these effects are not transient because these effects were seen after the dosing had ceased.

Q. Does your -- does Baker 2023 describe how these findings would be associated specifically with ASD?

A. Are you asking me how these effects are associated with ASD?

Q. No.

Does Baker -- the Baker 2023 article describe how these findings would be associated with ASD?

A. The Baker 2023 paper does not focus on ASD specifically.

Q. Does Baker -- the Baker 2023 article describe how these findings would be associated with ADHD?

A. The relevance of these findings to ADHD is discussed. The potential relevance of these findings to ADHD is discussed.

Q. And that's the anxiety discussed -- issues discussed in the conclusion?

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MS. HUNT: Objection. Misstates evidence.

You can answer.

THE WITNESS: The exposure of the study, acetaminophen prenatal and the epidemiology discussion, is focused on neurodevelopmental impacts of prenatal acetaminophen on ADHD. ASD is discussed in the introduction as well.

But the outcomes are discussed more agnostically for disease, and we do that intentionally because neurodevelopmental disorders are highly comorbid with each other. We intentionally don't try to pin results so tightly to one diagnostic outcome for multiple reasons.

One, because of these transdiagnostic effects. Also, the outcomes we found weren't so ASD-specific -- or, sorry, ADHD-specific.

Also, we are dealing with rodents. You know, rodents aren't

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little humans, as I've stated. ADHD-like outcomes in rodents aren't easy to model. It takes strong expertise to be able to do this work. We're very equipped to do that work.

So in our results, we talk about our results as we find them and are very conservative about how we do that.

Our RNA sequencing results we talk about in terms of pathways and avoid trying to overattribute these pathways to ASD and ADHD influences.

QUESTIONS BY MR. PADGETT:

Q. If you turn to the conclusion of Baker 2023 on page 11.

You state there -- there's a sentence that starts "It."

A. "It is also possible"?

Q. Yeah.

Quote, "It is also possible that ADHD is too complex a human disorder to be translated into human behavior," end quote.

As you sit here today, do you

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agree with that statement in Baker 2023?
A. What is -- what is attempting to be communicated here is that you may not be able to capture the full -- the full entity that is human ADHD in a single animal model. You have to compartmentalize it into symptoms and symptom domains. So essentially the idea that you can look for every aspect of ADHD in one animal model might be overambitious.
Q. Is it your opinion that the full range of ADHD in humans is captured by the entirety of the animal models for ADHD?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I believe that's outside of the scope of my mandate for this proceeding.
QUESTIONS BY MR. PADGETT:
Q. I'm -- no, I think -- I think it's very within your expert report, and it's relevant to this quote, this line, from Baker 2023.
My question is, is it your

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opinion that the animal models for ADHD collectively --
A. Okay. I understand.
Q. -- capture the full range of ADHD behaviors in humans?
A. Yes. That's a good question.
So I believe the animal models can capture the full range of the behavior -- behavioral sequelae that are exhibited in humans that are living with ADHD.
Q. Animals cannot?
A. Animals can.
Q. Animals -- I'm sorry. Animals cannot talk, correct?
A. Animals can communicate.
Q. Animals cannot -- do you agree that animals cannot talk like humans?
MS. HUNT: Object to form.
You can -- you can answer.
THE WITNESS: Animals can communicate with vocal communication.
QUESTIONS BY MR. PADGETT:
Q. Dr. Baker {sic}, my question is, can rats or mice communicate in the expressive language that humans can?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: Rats and mice do not have a spoken language that is as complex as humans do, but they do have vocal communication, and they do have a rich vocal repertoire that can be measured.
QUESTIONS BY MR. PADGETT:
Q. Are you consulting on any litigated matters currently besides this case?
A. No.
Q. Have you ever been involved in any other litigation involving acetaminophen exposure?
A. No.
Q. Have you ever been involved in any litigation involving ASD or ADHD?
A. I have not.
Q. Have you ever been involved in other litigation involving exposure to medication or chemicals and allegations of adverse health effects?
A. I have not.

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Q. Dr. Pearson, are you relying on any other expert reports for your opinions in this case?
A. I relied on Dr. Cabrera, Dr. Louie, Dr. Baccarelli, and Dr. Hollander.
Sorry. I reviewed Dr. Hollander; I didn't rely upon it.
Q. And to be clear, I'm asking if you relied on these other named experts. You already clarified you're not relying on Dr. Hollander.
Have you relied on Dr. Baccarelli, Dr. Cabrera and Dr. Louie for your opinions in this case?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I cite all of these reports that I just listed to you in my report and defer to them on a lot of their expertise. Their expert reports don't change my expert report.
So I drafted my full expert report before I reviewed theirs, and having reviewed their expert reports,

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it did not substantially change my expert report.
QUESTIONS BY MR. PADGETT:
Q. You said did not?
A. It did not change my expert report. So having reviewed theirs, I did not need to modify mine.
Q. At page 3 of your expert report, you describe, beginning of your discussion, a weight of evidence methodology that you reviewed published preclinical studies evaluating the effects of gestational and perinatal APAP exposure on neurodevelopmental disorders.
And you are not limiting your evaluation to ASD or ADHD specifically, correct?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: It's difficult for me to answer your question.
Can you -- can you elaborate a bit?
QUESTIONS BY MR. PADGETT:
Q. In your evaluation of this

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case, did you evaluate these animal studies based on effects related to neurodevelopmental orders {sic} broadly or just ASD or ADHD specifically?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: Animals don't have ADHD or autism, so, accordingly, I can't just -- I had to -- you know, my catchment for the preclinical studies has to include neurodevelopmental search terms that extend beyond ASD and ADHD. So it's beyond just ASD and ADHD.
QUESTIONS BY MR. PADGETT:
Q. Okay. And then you used the term "perinatal APAP exposure" there.
Can you define what you mean by perinatal there?
A. So the exposure window includes early postnatal exposures as well.
Q. And for mice and rats, can you tell me where the postnatal window ends if you're talking equivalent to human gestation and neurodevelopment?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: So it's -- I believe it states clearly in my report where that catchment was, but without looking super clearly, I believe it was either postnatal day 14 or 15? Yeah.
QUESTIONS BY MR. PADGETT:
Q. Was it PN -- is it postnatal day 10 or postnatal day 14?
A. Before I say for certain, I would need to find it.
But the first -- the first one or two weeks postnatal are equivalent to the third trimester in human brain development.
Q. Okay.
A. So that's the justification to include that as the -- in the exposure -- exposure window, to include the human prenatal equivalent.
Q. And did you include studies in -- animal studies in your weight of analysis evaluation that administered acetaminophen after the equivalent of the

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human gestational neurodevelopmental period of PN 10 or PN 14?
A. There are studies that continue the exposure beyond that window, but the requirement was the exposure needed to begin before that early postnatal period.
Q. I'll probably butcher the pronunciation here. There's a series of rat studies, the Blecharz-Klin studies. There's two, 2015, two studies, 2016, 2017, 2018 and 2019.
In those studies, the rats were dosed until they were two months old, 60 days old, right?
A. Yes.
Q. And if you could refer to page 48 of your report, PN 60, postnatal day 60, is the equivalent of a young adult. Agree?
A. I would agree with that.
In my narrative review of those studies, I acknowledge that extension of that window, clearly.
Q. And you mentioned that.
Did you knock off any points in

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your scoring evaluation for that?
A. I don't recall.
Q. Is your -- is your response that you do not recall knocking off points or that you don't recall whether you did?
A. I do not recall whether that was a scorable criterion or not, the exposure window.
Q. Okay.
A. I do not believe it was.
Q. You agree that administration of acetaminophen at -- in a rodent at two months old does not correspond to human gestation, right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Exposure starting at two months of age would certainly be well outside of the exposure window, but these animals were exposed prenatally in addition to postnatally.
QUESTIONS BY MR. PADGETT:
Q. So there's a couple of studies that you excluded. There's a long footnote 7. Do you remember a long footnote

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7 --
A. I do.
Q. -- of studies you excluded?
The Ishida 2007, Viswanathan 2019 studies, you excluded those because they involved administration of acetaminophen in four- to five-week-old rodents, right?
A. Yes.
Q. And your basis for excluding those but not the Blecharz-Klin series of studies is because the Ishida and Viswanathan studies didn't involve the equivalent of human gestation dosing?
A. The difference between those studies is that any effects of acetaminophen would be solely attributable to adult exposures.
Q. So if we talk -- I think you reference in your report that 20 -- that rat gestation is 23 days, right?
A. Approximately.
Q. Okay. If we add 10 days or 14 days on for postnatal equivalent of the third trimester of human gestation, that would be 33, 37 days, right?

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A. That sounds about right.
Q. And if you dose the rats all the way up to 60, we're talking another 45 days or so of post-human equivalent gestation dosing, right?
A. I'll grant that, yeah.
Q. And the testing, behavioral and biochemical testing, in Blecharz-Klin in those series of studies was immediately after the last dosing at 60 days generally.
Is that correct?
A. It depends on the study. I don't think they were all at 60 days.
Q. Were many?
A. I think some of them began -- began earlier.
Q. All right.
A. Some of the biochemical ones started earlier, I thought.
Q. In many of these studies, though, the rats were dosed longer, like 45 days longer, than the human equivalent of gestation and tested right after that dosing ended, correct?
A. They may have been, yeah.

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I'll also point out that if you're doing an observational epidemiological study, those individuals that are followed up, they're still getting acetaminophen postnatal as well. So it's -- it's not -- it's ecologically relevant in some ways as well.
Q. In this Blecharz-Klin series of studies, how are you able to determine -- how were you able to determine whether the effects observed in those studies occurred from those -- the dosing up through PN 10 or PN 14 versus the dosing from days 15 to 60?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: In the -- in the Blecharz-Klin studies, they do not have controls that would allow to discriminate the exact time point when the cellular, molecular, behavioral perturbation would occur.
On the other hand, there's still strengths in these studies because it's still demonstrating that these prolonged exposures starting in

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the prenatal periods are disturbing biochemical and behavioral changes.

Now, it does limit the critical window determination, these postnatal exposures as well, and that's why I fully acknowledge in my report the limitations of these studies. I acknowledge fully that that is a limitation, the post -- these postnatal windows as well.

QUESTIONS BY MR. PADGETT:

Q. But again, we don't know how -- you don't recall how that affected your scoring in your weight of evidence analysis, correct?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: The scoring system is to discuss the rigorousness of the study design. The scoring is not to -- is not -- is not to -- is not intended to -- the point of the scoring is not to be able to tell you whether every single study that's a part of the weight of the evidence is

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suitable for understanding acetaminophen and prenatal exposure windows and neurodevelopmental health outcomes.

The scoring system that I came up with is to understand the characteristics of the study and give a transparency into my work into understanding the parameters of controls and those sorts of characteristics of the study.

So not every aspect of the study got a score, but that's why there's a narrative box that came with it to where I disclose, like, here are strengths and weaknesses of these studies as well.

So not every aspect of the study has a score -- a score-driving aspect to it. It's unrealistic to expect that. This would be a thousand-page report if it did.

QUESTIONS BY MR. PADGETT:

Q. Dosing was given a score, though, right, as part of your weight of the

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evidence analysis?

A. Dosing?

Q. Yes.

A. Whether it had multiple doses or not, yes.

Q. But things like dosing duration or dosing amount, you didn't adjust the points given for a study based on differences there, just based on whether there are multiple doses given?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: There's an infinite number of ways that I could have designed the rubric. This is the system that I came up with. The exposure window was an inclusion criteria for the studies.

If pre -- if gestational dosing was included for acetaminophen and neurodevelopmental relevant outcomes were in the study, then it was included in the weight of evidence. That was not a scored criteria.

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QUESTIONS BY MR. PADGETT:

Q. If you could turn to page 47 of your report.

A. Okay.

Q. It's 46 to 47. There's a paragraph describing this -- what leads to a chart, a figure. And you've got different -- differently grayed or darkened dosing for a mouse from therapeutic sublethal toxic dose, lethal toxic dose, if untreated, and evidence of neurodevelopmental, neurological damage.

Do you see that?

A. I see it.

Q. Okay. The therapeutic dose you list there for mice is 200 milligrams per kilogram, correct?

A. That's correct.

Q. Okay. And that's the top end. That's the outer edge of the therapeutic dose you've listed there, right?

A. It is.

Q. Okay. And lethal toxic dose appears to be potentially anything above 350 milligrams per kilogram; is that right?

A. It's -- it's a spectrum,

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because it's hard to find exact numbers.
Q. Would you agree that the line that you drew here on lethal toxic dose of 350 milligrams per kilograms for mice in that figure?
A. I think it was maybe 325.
Q. Okay.
A. The reference numbers are 3 and 4 there.
Q. So 325.
A. I think those are coming from overdose studies where they're looking for liver damage. I don't think they're necessarily lethality studies, but...
Q. It's listed as lethal toxic dose, though, right, on Figure 23?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: If you look inside of the box on Figure 2.3, it says, "Note: Concentrations in delineations are approximate based on a survey of literature for oral. They do not account for individual strain

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differences. These are meant to be approximate."
QUESTIONS BY MR. PADGETT:
Q. Lichtensteiger 2015 only administered a dose of 360 milligrams per kilogram, right?
A. Okay. I'd have to look.
(Pearson Exhibit 71 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit 71.
A. Okay.
Q. Is that the Lichtensteiger 2015 study?
A. It is.
MS. HUNT: Counsel, before we start on a new study, I think we've been going about an hour and 20 minutes.
MR. PADGETT: Sure.
MS. HUNT: Can we take a break?
MR. PADGETT: Can we just finish this one?
MS. HUNT: Sure.

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MR. PADGETT: This question?
QUESTIONS BY MR. PADGETT:
Q. What was the dose used in Lichtensteiger?
A. I'm looking.
Q. As far as acetaminophen.
MS. HUNT: Counsel, do you have a copy for me or no?
MR. PADGETT: Sorry.
MS. HUNT: Thank you.
MR. PADGETT: I believe it's --
THE WITNESS: Buried in this paper, yeah.
QUESTIONS BY MR. PADGETT:
Q. -- Table 1.
A. It's Table 1.
Q. The...
A. 360.
Q. That was -- that's the -- that was the -- 360 milligrams per kilogram for acetaminophen alone, correct?
A. Yes.
Q. Okay. But this isn't -- this was included in your weight of analysis?
A. It was.

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Q. Okay. We already talked about Klein 20 -- or actually I'm gonna --
MS. HUNT: Can we take a break?
MR. PADGETT: Yeah, let's go ahead and take a break.
VIDEOGRAPHER: The time right now is 11:18 a.m., and we're off the record.
(Off the record at 11:18 a.m.)
VIDEOGRAPHER: The time right now is 11:36 a.m., and we're back on the record.
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, back from a little break.
Page 4 of your report. And I should be keeping better track, but I believe that was...
MS. KAPKE: It's 65.
QUESTIONS BY MR. PADGETT:
Q. Exhibit 65, your amended report, at page 4.
You have a statement about "preclinical studies account for confounding that may be present in epidemiology studies."

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And --
A. Can you show exactly where that is or tell me where exactly that was?
Q. You know what, strike that.
I'd like you to turn to pages 60 -- page 66, please.
A. Okay.
Q. And you talk about your weight of analysis methodology. And there you list five steps: problem; formulation, where you develop your hypothesis; evidence collection, where you establish lines of evidence and knowledge gaps; evidence evaluation, determine data reliability, uncertainty and relevance; and evidence-weighing, where you assign weight of evidence; evidence integration and reporting, weight of evidence conclusions, when you examine evidence coherence and the impact of uncertainty.
Those are the five steps of your weight of evidence analysis?
Is that --
A. Yes.
Q. Okay. And you talk about problem formulation on page 67.

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Your problem formulation evaluated in utero exposure to acetaminophen and neurodevelopmental disorders generally, right?
A. It's -- it starts by saying neurodevelopmental disorders, including ASD and ADHD.
Q. Okay. But it was not specific to ADHD and ASD, right?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: It goes back to my previous testimony that in preclinical literature, the preclinical studies have limitations in terms of being specific to ASD and ADHD because animal models -- they're animal models and in vitro models.
QUESTIONS BY MR. PADGETT:
Q. And then on page 69, you talk about evidence evaluation, and you characterize it as arguably the most important step in the weight of the analysis -- weight of evidence analysis, correct?

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A. It says, "perhaps most important," yes.
Q. Okay. If you'd jump ahead to the data reliability discussion at pages 72 to 76, please.
A. I'm there.
Q. Okay. And you discuss the importance of assessing quality and quantity, or sufficiency, and the consistency of data across the lines of evidence, right?
A. That's included in this area, yes.
Q. And you state, "The sufficiency refers to the quantity of data that addresses the hypothesis or problem, and consistency refers to the level of consensus and concordance among the data in the particular line of evidence."
Right?
A. I'm not sure where it says that exact statement, but --
Q. Page 73.
A. Consistency refers to the level of consensus and concordance amongst the data in a particular level of evidence.

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Q. Aside from a discussion -- and I think it's on page 128 of your report -- consistency is not necessarily necess -- or not necessarily needed. You don't discuss consistency among the studies included in each of your lines of evidence in this report, right?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: You're asking whether I discuss consistency within each of the lines of evidence?
QUESTIONS BY MR. PADGETT:
Q. Right.
A. I do. There's a table at the end of each line of evidence where consistency is discussed.
Q. And you're talking about the mouse and the rat tables?
A. Well, there's the -- there's the lines of evidence and then tables, and they discuss -- take us there.
Q. Let me ask it this way. Do you discuss particularly -- particular

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inconsistencies between studies on certain endpoint findings across these studies?

MS. HUNT: Objection. Form.

You can answer.

THE WITNESS: So the way that I perform my weight of evidence was not to contrast each and individual -- each and every individual study to see how they do and do not support one another or whether the -- each individual data set contrasts each other. That was not my goal.

QUESTIONS BY MR. PADGETT:

Q. So, and correct me if I am wrong, I don't recall a specific discussion of, say, rat study X we found this finding on a particular endpoint, which -- and address an inconsistency with rat study Y that found no change or something -- a change in a different direction.

You didn't do that kind of study-by-study analysis, right?

MS. HUNT: Object to the form of the question.

You can answer.

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THE WITNESS: The example that you gave would not -- would not be an appropriate way that an expert would do this, for multiple reasons.

One, as I explained multiple times, the directionality is not an appropriate way to look for things. Directionality is something that we -- that's sort of a face validity thing. Face validity is kind of lowest level of evidence for animal models in neuropsychiatric disorders. These studies aren't necessarily engineered to fill gaps of other studies.

The weight of an evidence is to look for the cumulative data across all of the different studies on the whole. It's not -- the goal of this endeavor isn't to say, are all of the puzzle pieces filled. It's to say that is there a total -- an abundance of evidence to suggest that acetaminophen is a developmental neurotoxicant that elicits the effects that are relevant to these health

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outcomes.

It's not to -- again, it's not what you're suggesting.

QUESTIONS BY MR. PADGETT:

Q. Let me give you an example. Let's take the five-choice serial-reaction time test, which is focused on attention as it relates to ADHD. That's the focus the -- of that particular assay in the animal model, right?

A. Yes.

Q. Okay. This is just an example.

Did you do an analysis of, across studies, the consistency for the endpoints in terms of changes seen or no changes seen on an endpoint like that --

MS. HUNT: Object to form.

QUESTIONS BY MR. PADGETT:

Q. -- as a part of your weight of the evidence evaluation?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: That was not my goal with my weight of -- weight of evidence analysis.

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QUESTIONS BY MR. PADGETT:

Q. I understand it's not your goal, but did -- you say it's not your goal, and then you -- so did not do that because that wasn't your goal, right?

MS. HUNT: Objection. Asked and answered.

You can answer it again.

MR. PADGETT: Object to form only, please.

MS. HUNT: My objections have been appropriate, and in fact conservative, compared to what some of the counsel for Johnson & Johnson have done. And I'm not -- I'm happy to argue with you about it if you want to take up more time on your record.

There's nothing inappropriate about my objections. I'd like to get back to the questioning.

MR. PADGETT: Well, I'll just remind you to object to form only, and we don't -- you know, if it continues beyond that, we don't want to have to deal with the Court.

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MS. HUNT: We'll see.
QUESTIONS BY MR. PADGETT:
Q. Go ahead.
A. The example that you're giving would not -- is not pertinent to the mandate that I was given. It would not be necessary.
Q. So you didn't feel it was necessary and therefore you did not do that type of cross-studies analysis of inconsistencies, correct?
MS. HUNT: Again, objection. Asked and answered.
You can answer.
THE WITNESS: So in my report, I do discuss where there's concordance across studies.
QUESTIONS BY MR. PADGETT:
Q. Do you discuss whether there's inconsistencies across studies?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: I do not recall offhand where I discuss whether there is or isn't inconsistencies.
But a weight of evidence

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analysis does not require inconsistencies of all studies to be evaluated.
QUESTIONS BY MR. PADGETT:
Q. Data quality, I think, is discussed pages 73 to 79 of your report.
For assessing data quality, would you agree that you created your own scoring system?
A. I would not agree that for assessing data quality I created my own scoring system.
Q. Can you identify a particular peer-reviewed, preexisting scoring system that you used? And I'm talking specifically as to a scoring system in putting together your scoring system in your weight of analysis -- weight of evidence analysis.
A. As I stated previously, the study design attributes, I put numerical parameters to those to add transparency to my evaluation of those.
Q. That's in your report. I understand that.
My question is, in doing that

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exercise, did you rely on a peer-reviewed, validated, preexisting scoring system that was already in existence?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I relied on the same evaluation system that I use when I peer-review grants and other publications. It's the same way that I evaluate other studies.
QUESTIONS BY MR. PADGETT:
Q. You use a scoring system when you peer-review grants or articles?
A. Yes. That's pretty common, actually.
Q. And are you saying it's similar to what you did in this weight of analysis evaluation?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: It's pretty analogous to evaluation criteria for any evaluation of publications or grants.

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QUESTIONS BY MR. PADGETT:
Q. Can you --
A. Grants submitted to granting agencies are scored on scoring systems, like a 1 to 5 system or a 1 to 2 system.
It's the same for peer-reviewed publications. It's numerical scoring systems based on innovation, based on quality of controls, and it's a very similar type of scoring system.
Q. And have you done that exercise outside of this litigation in the same manner that you did it with regard to your scoring system here in your weight of analysis -- or weight of evidence analysis described in your report?
A. I -- as I said, it's fairly analogous. Just as I said, I just co-opted it here to add transparency to the way that I evaluated the preclinical literature for the purposes of the weight of evidence.
And then in terms of publications, I'm using the OECD framework, which is a scientific approach to performing a systematic review.

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Q. You state on I think it's page 74 your scoring template that you used for each study. The parameters were direction of effect, controls, sample size, outcomes, multi-dose, whether there was multi-dosing, blinding, and bias conflict flag.

Is that right?

A. That's what's stated here.

Q. Okay. You did not define in your report what an insufficient control is, right?

MS. HUNT: Object to form of the question.

You can answer.

THE WITNESS: Well, in the text I refer to the table and give a little bit of context into what the parameters are that go into it.

QUESTIONS BY MR. PADGETT:

Q. What page are you referring to?

A. Let me find it. I think it might have gotten out of place accidentally.

Q. I can't imagine that, a 130-page report.

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A. I think it accidentally got shifted around. Bear with me, please.

Maybe I didn't expand on it any further than what's in the table.

Q. And which table are you referring to?

A. Table 1.

It's the blank scoring template.

Q. Okay. Table 1 is the extent of your explanation of -- or definitions or explanation of these -- the parameters that we just discussed?

A. Not completely. In the narrative explanation for a lot of the studies, there's oftentimes, but not always, but oftentimes there's additional clarification as to why a score was given.

The scores aren't meant to be used as an actual grade, if you will. It's just meant to give sort of an ultimate positive or negative for a weight towards there's evidence for or to the contrary in the end.

Q. And beyond this table and what

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you're referring to in some of the -- your summaries of the studies, did you explain across your weight of evidence analysis what the differences between acceptable and a good control are?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: I don't think I provided much other explanation of that. But the thing you have to keep in mind is that the weight of evidence methodology ultimately requires expert knowledge, and that's what I'm bringing, is my expert knowledge and my, you know, almost 20 years of peer-reviewing hundreds of publications, writing dozens of publications. So I'm bringing that knowledge in my expert ability to adjudicate on that.

QUESTIONS BY MR. PADGETT:

Q. In your description of your weight of analysis -- weight of evidence analysis, you do not define what an acceptable sample size is, correct?

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A. I give some descriptions of that in my expert report.

Q. You don't in any way quantitatively define, depending on the type of study, what an acceptable sample size is, right?

MS. HUNT: Objection. Asked and answered.

You can answer.

THE WITNESS: I don't recall offhand where exactly it is, but I give some general parameters as to what's oftentimes needed. But it really is -- it depends on the study. It's prescriptive to the study what sorts of sample sizes are oftentimes needed.

QUESTIONS BY MR. PADGETT:

Q. Can you explain to me with regard to outcomes what distinguishes a poor, moderate and good quality outcome as referenced here on page 74, Table 1?

A. The quality of the outcomes might have to do with the extent of the outcomes. So a study might have only one

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outcome that's relevant, but because it's one outcome, the score might not be as high.

Another study might have outcomes that are on their own not quite as relevant, but because the study has more of them, the outcome score might be higher.

Another study might have only a few outcomes, but each of them are very, very high.

So to give you an example of a study that's looking for ASD-relevant behavioral outcomes or ASD-like outcomes as a function of acetaminophen exposures, if they have the three-chamber socialability test and they have gene expression and they have, you know -- let's see, what would be another good example -- they have ultrasonic vocalizations, maybe they only have those three outcome variables, but those are highly relevant, highly important variables themselves, so the outcome score would be higher. I don't think there's a study that had those three things specifically.

So it -- you know, there's not one hard-and-fast rule that says you have to

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have three outcomes. You can have one outcome that's highly -- high quality, but you still might have a moderate outcome score because you have fewer high quality. You might have a higher number that are lower quality, for instance.

So it's multi-dimensional, the way that this is calculated.

Q. And did you -- and so is outcome as used here, outcomes, is that essentially the same as endpoint findings in a study?

A. Yeah. That's fair.

Q. Okay. And within individual studies on various endpoint findings, did you do an analysis for purposes of scoring of whether those endpoint findings, there were more than one for a particular behavioral effect, were consistent within the study pursuant to the animal models that you laid out at pages 39 to 46 of your report?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: I want to make

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sure I understand your question.

So are you asking about whether the outcome score that I give depends on what results they find?

QUESTIONS BY MR. PADGETT:

Q. Yes.

A. The score that I give is independent of the outcome, what they find. It's the measures that they --

Q. Yeah.

A. -- choose to use. The score is independent of what they find.

Q. And let me ask this. Whether or not you put a study on the plus side of the scale or the negative side of the scale, did you do an analysis of the consistency among assays for particular behavioral endpoints within a study?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: My understanding of your question is whether the study ended up on the plus end of the scale or on the negative end of the scale had anything to do with the

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consistency of the measures within the outcomes.

Is that a fair --

QUESTIONS BY MR. PADGETT:

Q. Yes.

A. No. It has to do with whether the effects within those outcomes suggest that acetaminophen affects neurodevelopmental, neurochemical or neurobehavioral outcomes that are relevant to ASD-like or ADHD-like health.

Q. So going beyond one specific behavioral effect, I'm going to provide you a hypothetical.

If a study showed one assay with a statistically significant finding with regard to increased activity, another finding on increased activity that was no change -- are you following me? That -- that's the activity domain -- and then another part of that same study looked at -- or another set of assays looked at inattention and impulsivity and found no changes consistent with the ADHD model, would you put that one effect of increased activity as sufficient to

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put it in the plus column?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: In this particular -- this hypothetical that you've given me, if there was such a study that looked at some measure of impulsivity and attention and activity, and in two tests of activity -- and one of them found increased activity and another one no change, and then the other test found no change --
QUESTIONS BY MR. PADGETT:
Q. For impulsivity and attention, correct.
A. -- it would go in the plus --
Q. Okay.
A. -- certainly.
Q. Okay. In pages 76 and 77 of your report, you discuss different methods of administration commonly used in preclinical developmental neurotoxicity studies, right?
A. I see this.
Q. Okay. Would you agree that

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doses by injections bypass the liver in first-pass metabolism that would occur if a drug was administered orally?
A. Injection of drugs, a lot of the initial bolus of that drug would bypass first-pass, but it'll get there eventually. Just takes a little bit longer.
Q. At a -- depending on the metabolism associated, it would be a lower amount, correct?
A. Are you asking if the amount of the drug would be -- the amount of the drug that's metabolized would be lower?
Q. In a -- if you're going through the liver in first-pass metabolism.
MS. HUNT: Object to form.
You can answer.
QUESTIONS BY MR. PADGETT:
Q. Than an injection route.
A. Oral versus injection?
Q. Yes.
A. The kinetics would certainly be different.
Q. And the kinetics for oral involving first-pass metabolism in the liver

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would result in lower concentration, correct?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: It's hard to answer that question because it's -- it depends on the route of injection. If you -- to give you an example.
So if you give an intravenous versus oral, the Cmax is certainly very different. There's data that supports that. But, for instance, the area under the curve is very similar.
So, you know, it's -- are you asking about bioavailability? Are you asking about area under the curve?
The first-pass metabolism is different. The Cmax is different.
So route of administration is an important consideration, but bioavailability can be very similar.
QUESTIONS BY MR. PADGETT:
Q. You agree that drug and metabolite concentrations from an injection would be different from those that would occur via oral exposure?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: As I said, the bioavailability can be very similar, but the Cmax can differ.
QUESTIONS BY MR. PADGETT:
Q. And I think after the table on page 77 of your report, you note that orally administered APAP products are the focus for your inquiry and, as such, tests that utilize other routes of administration require an additional degree of extrapolation.
Would you agree that the majority of the studies included in your weight of evidence analysis did not use oral administration of acetaminophen?
A. I don't necessarily agree. It depends on the species.
Q. Well, let's go to --
A. Many of them use injection. I would concede that.
Q. If we go to page 84 on rat studies.
Seven of the 14 rat studies used oral dose exposure route, right?

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MS. HUNT: Object to form.
You can answer.
THE WITNESS: I see that many of them used oral, yes.
QUESTIONS BY MR. PADGETT:
Q. Seven of 14, correct?
A. No, that's not correct.
Q. Can you explain what --
A. Gavage is oral.
Q. Is gavage go -- gavage goes through a first pass?
A. It does.
Q. Okay. So that would be ten total --
A. Yes.
Q. -- of 14, right?
A. Yes.
Q. Okay. And for the mouse studies in your chart at page 101, the -- five of the 15 studies use -- there used gavage or oral exposure route, correct?
A. I think it's actually a different number, but it's -- yeah, many of them used injection. Many of the mouse studies used an injection.

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Q. Overall, between the rat and the mouse studies, about half of them used injection as opposed to gavage or oral, right?
A. On the order of that, yeah.
Q. Yeah.
What do you mean by "an additional degree of extrapolation" there on page 77 of your report?
A. I'm not sure what I meant with that statement. I think -- I think that's -- I think that's probably something I wrote late, and I -- it's a bit nonsensical.
Q. Would your highest-scored study -- and I believe it's page -- it's a mouse study, page 101 -- is the Harshaw & Warner study. You gave that a 9 total, correct?
A. I think I might be off by pages. Oh, I'm -- we're --
Q. Looking at your amended expert report.
You're right.
A. Okay.
Q. The amended one is slightly

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different. Page 100.
A. Threw me off here. Okay.
On 100 I have Viberg.
Or are you looking at the table?
Q. I'm looking at the table.
A. Oh, okay. Yes.
Q. There are a number of studies on your initial report that are not on the list of studies on page 100.
I guess my question is, did you make changes to this chart between your initial report submitted on -- the first report and this amended report?
A. I do not remember if this chart was changed. I believe there was one table that was corrected because there was a duplication in the -- a table, but there wasn't any substance that was changed.
Q. So as far as mouse studies, we're talking three oral, looking at page 100, and six injection studies, right?
A. That is what I see here.
Q. And Harshaw & Warner is given the highest score out of all of these studies

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in your weight of evidence analysis, right?
A. It is.
Q. And Harshaw used a subcutaneous injection, right?
A. They used a subcutaneous injection.
Q. Was there any discounting of points at all based on the route of injection due to that additional degree of extrapolation that you mention on page 77 of your report?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: No. No difference of extrapolation is needed.
Again, the control animals would have received an injection as well in this study, so that's perfectly controlled for, the injection itself. So they -- the experimenters have accounted for that manipulation itself.
QUESTIONS BY MR. PADGETT:
Q. Did all of the studies included in -- and you reference that as an important

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factor in offsetting any differences in the route of administration, is that the controls through vehicle received the same -- or water received the same type of dosing route, right?

A. It's incredibly important.

(Pearson Exhibit 73 marked for identification.)

QUESTIONS BY MR. PADGETT:

Q. Okay. Dr. Pearson, I'm going to hand you what's been marked as Exhibit 73 and ask you if you recognize that study.

A. I do.

Q. And that is the Beck 2001 study, correct?

A. Yes.

Q. Does this -- and you can look at your summary in your report on it. Does this article indicate that if controls were gavaged in this study?

A. Yes. So I noticed in the defense expert report that they caught, which I may have missed, that they did not use an appropriate control in this study.

Q. Because gavage creates stress

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that to be an appropriate control would need to be replicated in the same type of gavage administration in a control, right?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: Yes.

QUESTIONS BY MR. PADGETT:

Q. Okay.

A. But I would like to point something out. So this study is not completely at issue because they have multiple time points, they have temporal data, which can be used as controls. So later time points can be used as their own controls.

So fortunately for these authors, the ten-hour, 23 -- ten-hour time point can be used as control for the 20, 30 40, 50 hour.

So the zero time point that's not controlled for is unreliable because they don't have a control gavage time point. But the other time point can be used as a control for the subsequent time points.

Q. I'm going to hand you what's

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been marked as exhibit -- previously marked as Exhibit 43. I believe this was from Dr. Louie's deposition.

Do you recognize that study?

A. I do.

Q. Does this study indicate -- study article indicate if controls also received enteroperitoneal injections like the treated animals did?

A. I was not able to find in this study whether or not the four different time points received a control injection or not.

Q. But would you agree, if we look at page 84 of your chart -- I'm sorry -- page 83 of your report, Koehn 2020 -- or actually, in your description of Koehn 2020, it was given the highest score, a 2, for controls?

A. Yeah, I would amend that. That's a mistake.

Q. Okay.

A. Now knowing that, I would give it a zero.

Q. Do you think it's proper for study authors to use untreated controls?

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MS. HUNT: Object to -- sorry. Are you done?

MR. PADGETT: Yes.

MS. HUNT: Object to form.

You can answer.

THE WITNESS: In general, researchers should use vehicle-treated controls for their studies to have the best controls. That's why I have it as a scorable criterion.

In the Koehn, et al., study, there's aspects of the study that are controlled. So for some of their -- some of their comparisons where they have cannulated dams in some of their pups, they have -- they have controls there.

But it's true for the acetaminophen conditions with the subchronic four-dose treatment, it does not appear as though they have the vehicle control, which is, again, why I would revise the score for that particular study as well as the Beck study. It is important.

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(Pearson Exhibit 72 marked for identification.)

QUESTIONS BY MR. PADGETT:

Q. I'm going to hand you what's been marked as Exhibit 72 and ask, do you recognize that document?

A. I do recognize this document.

Q. Okay. And that is the Tyl article that's referenced many times in your report, correct?

A. Yes.

Q. Come back to that, but I want to ask you about the -- in the Koehn study again.

If you turn to page 4 --

A. Of Koehn?

Q. Yes.

At page 97 of your report, if you want to look at that, you scored the sample size as appropriate, with a score of 1 for Koehn 2020.

Do you disagree with that?

A. Koehn 2020 has a lot of different comparisons. I think for some of their analyses they're well-powered; for some

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of their analyses they have low sample size. It's a bit of a -- it's a bit of a mixture.

Q. And if you turn to page 4 of Koehn under animals, it says, "Animal numbers were" -- it's kind of about the middle of the paragraph. "Animal numbers were based on previous experiments of such" -- "previous experience of such experiments and where the minimum number required to detect a significance between groups at P less than .05."

Do you see that?

A. I see it.

Q. Okay. Is that a scientifically appropriate method for determining sufficient sample size?

A. It can be.

Q. And at times it cannot be, correct?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: When designing and conducting research, researchers can rely on their experience in understanding how many animals are

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appropriate to use for a particular application.

QUESTIONS BY MR. PADGETT:

Q. The results section on page 7 notes instances where only four animals were used.

Do you -- do you think that is a proper sample size?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: A sample size of four can be appropriate depending on the study.

QUESTIONS BY MR. PADGETT:

Q. Depending on the study.

How do you determine if there's a sufficient number of pregnant animals to ensure that an adequate number of offspring are produced for developmental neurotoxicology evaluation?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: It's a case-by-case study. It depends -- it really depends on what you're doing,

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what the parameters are, if it's regulatory, if it's nonregulatory, if it's exploratory, if it's confirmatory. It very much depends.

QUESTIONS BY MR. PADGETT:

Q. Generally, should an a priori power analysis be used to determine the animal -- the number of animals needed to see an effect of a certain size?

A. I would refer back to my previous answer. It depends on if it's an exploratory study or if it's a confirmatory study, if it's a regulatory study, if it's -- if it's exploratory empirical study.

Q. You did an a priori analysis as a part of the Baker 2023 study, right?

A. Can you state that question again? I'm sorry.

Q. You did an a priori analysis to determine the number of animals needed as part of your Baker 2023 study, right?

A. I'm trying to recall. For the IACUC approval we did, yes.

Q. Okay. One of the things you discuss out of the Koehn 2020 study -- and

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this is on page 96 of your summary -- of your report where you summarize it -- is that there was an increase of AFP levels in treated dams.

What again are -- what again is AFP?

A. I believe it's alpha-fetoprotein --

Q. Okay.

A. -- if I recall correctly.

Q. Given that -- and you point that out in your report, right?

A. Yes.

Q. Okay. And given that -- if you look at Figure 8 of Koehn, "AFP data are based on a number of 1 or 2 per group" -- would you agree the differences could possibly be due to individual variability?

MS. HUNT: Can you give me a page number for Figure 8?

Sorry, it's a long paper.

THE WITNESS: Yeah, it is.

MR. PADGETT: Yeah, it is long. That would be page 22.

MS. HUNT: Thank you.

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THE WITNESS: So you said that in my report I said -- I just -- from what I read from my report, I just say that they display full-length gels for AFP Western Blots. I don't say AFP is elevated.

QUESTIONS BY MR. PADGETT:

Q. I believe it's page 96 of your summary.

A. I don't think I drew the conclusion that AFP was significantly changed anywhere in my report.

I refer to the fact that they give the full-length gels, which I appreciate because it shows they're transparent.

And then I also say that some analyses are qualitative, for example, the permeability metrics and the alpha-fetoprotein Western Blot. So I'm saying that they're not including statistics for that, which is a criticism.

Q. I'm sorry, it's on page 95, going over to 96.

A. Okay.

Q. You state, quote, "Results from

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the placental permeability measures showed that placental transfer was potentially affected by APAP treatment and demonstrated increased levels of AFP detected in blood plasma of dams treated with APAP, indicative of elevated fetal-to maternal leakiness of placenta," end quote.

Did I read that right?

A. You did read that right.

Q. Okay.

A. But I did not say it's sufficient.

And additionally, the exhibit that you gave me before, which is -- now I've lost it because my pile is huge here. But the Tyl, et al., or Tyl, et al., talks about there's biological significance and there's statistical significance.

The biological significance of this might be meaningful, even if it's not statistically significant. So it might be worth mentioning, even if it's not statistically significant.

Q. Can you turn to page 33 of the Koehn study?

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A. 33. I'm there.

Q. You see how it's -- the italicized is the author response, and the non-italicized are comments from reviews, correct?

A. Yes.

Q. Okay. Let me ask you this.

Are you familiar with the F1000Research journal platform?

A. A little bit.

Q. Have you ever -- have you ever submitted any study articles for publication to F1000Research?

A. I have not.

Q. Have you ever submitted any study articles to a journal platform that publishes the study before peer review is conducted?

A. I have not.

Q. Would you submit a study article done at Columbia University to a re -- a journal platform that publishes article prior to peer review?

MS. HUNT: Objection. Scope. You can answer.

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THE WITNESS: I would consider it. I think it's an interesting model.

QUESTIONS BY MR. PADGETT:

Q. What's a -- can you explain to me what's a positive control?

A. Generally speaking, a positive control is using something to elicit a response in your system, that you know would elicit a response in your system, so that you can demonstrate that you can measure what you intend to measure.

Q. And you indicate on page 7 of your -- 8 of your report that the absence of a positive control data does not necessarily disqualify a study from consideration unless there's a reason to believe the experimental lab -- or experimenter or lab is not capable of reliably measuring the outcome of interest, right?

A. I maintain that --

Q. Yeah.

A. -- opinion.

Q. If you turn to Exhibit 11, which is Tyl. I'm sorry, Exhibit...

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A. Yeah. 72?

Q. 72?

Page 353 under Section 3.12, Positive Controls.

Do you see that?

A. 353 or 252? I'm sorry?

Q. 353.

It's immediately under 3.12, Positive Controls. Dr. Tyl states that "a critical element in the review of a DNT study is availability of adequate positive control data."

Do you agree with that statement?

A. I agree -- I would agree with the statement under certain contexts.

Q. And what -- under what context would you disagree with Dr. Tyl's statement there?

A. I think it would be easier for me to agree with it on -- it would be easier for me to do the opposite, to do the inverse of that.

I think having positive control data is incredibly important under regulatory

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context, under GLP, like Good Laboratory Practice, pharmaceutical, risk assessment situations.

If you're doing empirical research and you have laboratory scientists that have good track records and you're doing relatively straightforward assays, it's not necessarily applicable.

Q. Do you agree that Dr. -- that Dr. Tyl's article here that you've quoted from and relied on extensively in your report is actually focused more on regulatory develop -- neuro -- neurotoxicology studies and --

A. I think its general applicability as to -- is oftentimes to regulatory.

Q. In evaluating the evidence included in your weight of evidence evaluation, you applied the same scoring system for in vivo and in vitro studies, right?

A. I used the same scoring system for an ex utero and in vivo, yes.

Q. Are you distinguishing between

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in vitro and ex utero?

A. Ex utero.

I -- I distinguish them because there's -- they're -- I'm -- in an umbrella sense, they're -- they can be lumped together, but there's also some distinctions between them.

Q. Would you agree that the con -- first of all, what is publication bias?

A. Publication bias is a phenomenon whereby people could selectively publish things that only support -- or could fail to publish things that don't fit their idea of what they think should happen.

So null findings don't get published, or only null findings get published, for instance.

Q. Would you agree that the concept of publication bias weighs in favor of published studies ending up on the plus side of your scale in your weight of analysis -- weight of evidence evaluation done here?

MS. HUNT: Object to form.

You can answer.

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THE WITNESS: I would not necessarily agree with that. There are null studies that are in my weight of evidence analysis.

QUESTIONS BY MR. PADGETT:

Q. Is there any other null study other than Saad 2016 in your weight of evidence analysis?

A. Yes.

Q. What one or ones?

A. They are there. In the in -- the in vivo, ex utero, there are null studies. There are multiple -- there's more than -- yeah, let me find them.

Do I need to find them, or do you want to --

Q. Are there any in vivo studies listed at pages 83 or 81 in your -- those two tables of mouse and rat studies --

A. Yes.

Q. -- other than Saad that are -- that were null?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: Yes, Philippot,

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et al., 2021.

QUESTIONS BY MR. PADGETT:

Q. Okay.

A. I don't believe there were any in the rat.

So to elaborate, I think publication bias can go -- can work in both directions. There's an interest -- publication bias could work in the interest of both perspectives.

Q. When you say that, do you mean that there's -- what do you mean by "both directions"?

A. "Both directions" meaning that there's people who think that -- in this particular case that acetaminophen is a developmental neurotoxicant that can lead to these health outcomes. There's people that believe that that's not the case.

So people could perform studies and then only study those -- only publish studies that support that perspective.

Q. You're speculating on that right now, right?

MS. HUNT: Object to the form

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of the question.

You can answer.

THE WITNESS: We've been doing plenty of hypotheticals here today, so...

MR. PADGETT: I'm at a breaking point if you want to take the lunch.

THE WITNESS: Lunchtime?

VIDEOGRAPHER: The time right now is 12:36 p.m., and we're off the record.

(Off the record at 12:36 p.m.)

VIDEOGRAPHER: The time right now is 1:35 p.m., and we're back on the record.

QUESTIONS BY MR. PADGETT:

Q. Dr. Pearson, do you believe that postnatal -- do you believe that use of APAP in human offspring after delivery is a risk factor for ASD or ADHD?

A. I haven't evaluated the comprehensive weight of evidence to determine whether postnatal use of acetaminophen use is associated with ASD and ADHD, so I'm not able to determine that.

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From a biological plausibility, I think it's possible.

Q. You just said it's possible, but as you sit here today, no conclusive belief on whether postnatal use of APAP in offspring after delivery is a risk factor for ASD or ADHD?

A. As I mentioned, I haven't done a full weight of evidence analysis on that particular topic, so I can't say for certain.

But as I mentioned, given the mechanism of damage of acetaminophen on neurological systems, and given that the brain isn't fully developed in the postnatal period, I believe it's plausible.

Q. You said possible first, now it's plausible?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: I think possible and plausible are within the same realm of -- can be used interchangeably.

QUESTIONS BY MR. PADGETT:

Q. Okay. Do you think a child's

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use of APAP after delivery is a confounder for human studies assessing in utero exposure?

A. You're asking me whether I think a child's use of acetaminophen in the postnatal period is a confounder?

Q. Let's say perinatal period after delivery. Is that a confounder for human studies assessing in utero exposure?

A. I'm not familiar enough with that to know whether that's a confounder or not.

Q. Do you intend to offer opinions in this litigation that potential use of APAP in human offspring causes ADHD or ASD?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: Could you repeat the question, please?

QUESTIONS BY MR. PADGETT:

Q. Yes, definitely, based on what I see here.

Do you intend to offer opinions in this litigation that postnatal use of APAP

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in human offspring causes ADHD or ASD?

A. I reserve the right to offer opinions based on any evidence that I'm -- that's made available to me that I can review.

Q. As you sit here today, recognizing your reservation based on additional evidence, do you -- as you sit here today, do you intend to offer opinions in this litigation that postnatal use of APAP in human offspring causes ADHD or ASD?

A. This is outside of the scope of my mandate. The mandate that I have been given for this particular proceeding is to evaluate the preclinical evidence as to whether acetaminophen is associated with the particular health outcomes. So I haven't performed a weight of evidence analysis on postnatal human exposures to acetaminophen and those health outcomes.

Q. In light of the fact that you have not performed the weight of evidence analysis of postnatal use of APAP in human offspring, is it fair to say you do not intend to offer opinions at this time in this

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litigation that postnatal use of APAP in human offspring causes ADHD or ASD?

A. Respectfully, my understanding is, is that this point of the phase I of this litigation is general causality about prenatal exposures to acetaminophen and ASD and ADHD. And my expert testimony has to do with the preclinical literature and the weight of evidence that I performed pursuant to that.

You're asking me about something completely different, and I've not reviewed the literature, nor have I been offered any documents that I can review with respect to that.

Q. And my question is, in light of what you just said, do you agree at this point in time you do not intend to offer opinions that postnatal use of APAP in human offspring causes ADHD or ASD in this litigation?

A. As I said previously, if I'm given the opportunity and other information and other literature, I would reserve the opportunity to offer an opinion at such time.

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Q. I understand your reservation.

But as you sit here today, do you intend to offer an opinion on postnatal use of APAP in human offspring as to whether it causes ADHD or ASD?

MS. HUNT: Objection. Asked and answered.

QUESTIONS BY MR. PADGETT:

Q. As you sit here today.

A. I do not wish to give an opinion on that right now because, as I said, that's outside of the scope of my expert testimony today.

Q. And you have no intent to give that opinion right now?

A. I have been not -- I have not been asked to give an opinion on that to date.

If I am asked to give an opinion on that, I reserve the right to give an opinion on that, given sufficient time and literature.

Q. We talked earlier about the Koehn 2020 study, and that involved use of a radiolabeled drug, right?

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A. I believe Koehn used a tritiated acetaminophen, if I recall correctly.
Q. Is that a radiolabeled?
A. It is.
Q. Okay. The study -- did the study provide any information on -- would you agree that the levels of acetaminophen in that study are at a single point in time?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: You're asking me whether in Koehn that the level of acetaminophen is at a single point in time?
QUESTIONS BY MR. PADGETT:
Q. Is measured at a single point in time.
A. I think you would have to clarify your question a little bit.
The level of acetaminophen is measured in different compartments in the Koehn, et al., study.
Q. At individual points in time.

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In other words, the study doesn't provide information on how quickly those levels would change over time, right?
A. Is there -- is there something you can point me to in the study that you're referring to? Because I'm not necessarily following what you're getting at.
Q. You mentioned that it looked at different areas of the brain. And my question is, when they look at the levels, those are for a single point in time for whatever area they're looking at. It doesn't assess across time in terms of those levels. That's my question.
A. So in the Koehn, et al., study, they looked at gene expression in the brain and the placenta.
You're saying that I testified to something about different regions of the brain. I'm not sure to what you're referring to that I stated.
Q. Are you looking at 2020 or 2019?
A. I would pose the question to you on -- you're the one who brought up the

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study.
Q. Are you currently looking at the 20 -- Koehn 2019 or Koehn 2020?
A. I -- in front of me I have Koehn 2020.
(Pearson Exhibit 76 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you -- I'm going to hand you what's been marked as Exhibit 76.
Is this the Koehn 2019 study?
A. This is Koehn 2019, yes.
Q. Okay. And did this use radiolabeled acetaminophen?
It's right there in the abstract, radiolabeled drugs, right?
A. One point of clarification. I don't know that I used this study in my weight of evidence analysis. I think I used this study in my background.
Q. Okay.
A. I just want to make sure that's on the record.
So when you referred to it

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earlier, it threw me off because this was not in my weight of evidence. So let me just make sure we're on the same page.
So in the abstract, you're indicating that they -- they say that they use a radiolabeled drug.
It does say that they used radiolabeled substances in rats.
Q. Okay. And for the doses given, my question is, did they assess the levels and whether they changed over time in Koehn 2019?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: Let me take a moment and look at their figures.
They did. Figure 6.
QUESTIONS BY MR. PADGETT:
Q. Figure 6?
A. Yes, on page 14. Bottom panels, acute administration and chronic administration.
Q. I'm talking for individual doses. Did they measure the levels for an individual dose at different points in time

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over time? That's my question.
A. Yes, that's what's being measured here. They're measuring deprecations per minute, which is what the radiolabeled gives you.
Q. Okay.
A. If you put tritium onto a drug, it decays. It's what a radioactive element does. It -- the protons within the nucleus of that decay. And if you put it inside -- inside of a counter, it measures the deprecations. And so this is a measurement of how much a drug -- drug is in that sample.
Q. And it was over the course of one minute, did you say?
A. No. The course of, it looks like, 150 minutes.
Q. Okay. Was there a comparison between the levels examined there in fetus versus pregnant females?
A. Yes.
Q. It wasn't adults that were nonpregnant females?
MS. HUNT: Object to the form of the question.

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You can answer.
THE WITNESS: My initial answer was correct.
QUESTIONS BY MR. PADGETT:
Q. Okay. And I'm looking at page 8, table...
A. Figure 6 on the different lines show the dam versus the fetus.
Q. And I'm looking at page 8, Table 5. That's what I'm asking about, to be clear.
And I guess I'm specifically looking at adults or nonpregnant females and littermates of both sexes were included in the E19 or P4 age groups.
The comparison there was made between the offspring and nonpregnant females, right?
A. That appears to be between offspring and nonpregnant animals.
Q. Okay.
A. But as I mentioned in Figure 4 -- or Figure -- what were we looking for? -- Figure 6, that's between the dam and the maternal plasma versus the fetal plasma.

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Q. And we talked about F1000Research previously, but based on the front cover page where it says "first published" --
A. Yes.
Q. -- August 7, 2019, and latest published, August 7, 2019, would you agree that there were no revisions made to this article after initial publication without peer review?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I wouldn't know because I didn't download this. I haven't looked.
QUESTIONS BY MR. PADGETT:
Q. This Koehn 2019 used injection method, right?
MS. HUNT: Object to form.
You can answer.
QUESTIONS BY MR. PADGETT:
Q. IP injection?
A. I would have to look at their methods briefly to recall.
It says on page 5, in all

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experiments involving postnatal animals, injections were at IP. In pregnant animals, radiolabeled marker was given intravenously. Fetal animals were individually injected IP while still in the intrauterine horn and -- the uterine horn. And so a variety of injection --
Q. Okay.
A. -- routes.
Q. Do in vitro studies capture the inherent complexity of organ systems?
MS. HUNT: Object to form.
You can answer.
QUESTIONS BY MR. PADGETT:
Q. In an animal?
A. Some in vitro systems can capture some aspects of organ systems, but they cannot -- they have limitations in terms of capturing multi-organ systems in the entirety of an entire organism.
Q. And they cannot account for interactions between cell and biochemical processes that occur in a living animal, right?
A. I would not necessarily agree

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with that statement.
Q. Would you agree that they cannot account for all of the interactions between cell and biochemical processes that occur in a living animal?
A. In vitro systems cannot account for all cellular and biochemical interactions of an intact organism, that is true.
Q. And they do not have absorption, distribution, metabolism or excretion processes in place, right?
A. They can have -- they can have all of those processes.
To elaborate, so in vitro systems can include each of those processes.
Q. Can include all four at the same time?
A. So organ-on-a-chip systems. Transwell systems. There are advanced in vitro systems that can incorporate hepatic kidney-type systems and multi-organ-on-a-chip systems that -- that can capture a lot of the ADME properties.
Q. And not to the -- would you agree not to the same extent as a living

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organism?
A. In vitro systems cannot capture every aspect of a full, complete organism.
Q. And you discuss in your report in silico data, right?
A. I discuss in silico data, yes.
Q. And that has major limitations in modeling human health and disease, correct?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: In silico systems can have certain limitations.
QUESTIONS BY MR. PADGETT:
Q. Would you characterize them as major limitations?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: It would depend on the application. They can have -- on the contrary, they can have major strengths.
QUESTIONS BY MR. PADGETT:
Q. If you turn to page 126 of your report.

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There is the -- the only paragraph of text there, as opposed to the tables and charts, this -- that paragraph relates to Comparative Toxicogenomics Database.
Is that right?
A. Yes.
Q. But you're also -- you also note that the relevance -- reliability is low to medium for the in silico line of evidence, right?
A. That's correct.
Q. The relevance is low, and the weight assigned is low, right?
A. That's what it says.
Q. Okay. And that is because, as you note here, this type of high through -- quote, "high through-put data have several major limitations in modeling human health and disease," end quote.
Is that -- did I read that correctly on page 126?
A. You read that correctly.
Q. Okay. And mod -- with regard to modeling human health and disease, the

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major limitations would include ASD and ADHD, right?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: ASD and ADHD are components of human health and disease.
QUESTIONS BY MR. PADGETT:
Q. You discussed early in -- well, I guess about page 124, you talk about that APAP has been tested in 970 assays in something known as the EPA ToxCast dashboard?
A. Yes.
Q. And of those 979 assays you identify here on pages 124 to 125, four that showed active calls; is that right?
A. That's correct.
Q. Can you describe specifically how these four active calls support a specific finding of acetaminophen as a causal -- that acetaminophen can cause ASD or ADHD?
A. On a weight of evidence analysis, you don't rely on one level of

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analysis to -- or level of evidence to support a causal framework. You rely on the totality and multiple levels of evidence.

So to more directly answer your question, I wouldn't rely just on this single data to do that. But -- yeah.

But in the -- in the full weight of evidence analysis, these kinds of results can be supportive in that these assays support the specificity of the types of effects.

So the first assay where you have activity and relatively low -- rather high sensitivity where you have a low AC50 is androgen receptor. And we know that acetaminophen has activity on androgen receptor, so that makes intuitive sense from a toxicological perspective.

The second assay is a nuclear hormone receptor, a progesterone receptor.

The third one, in HepaRG cells, which are hepatocytes, it makes sense that you have CYP450 activity there.

And the last one is SOX activity, which is essentially a

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transcription factor that's involved in development. So in that sense, the development's maybe not surprising given the neurodevelopmental activity that we're interested in.

Q. Did you actually go into the EPA ToxCast dashboard and review the data that these four calls -- assays were reproduced in your report?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: Are you asking whether I read more about these specific assays?

QUESTIONS BY MR. PADGETT:

Q. Strike that.

Did you go into the EPA ToxCast database and look at the information on that database that's reflected in your report at pages 124 to 25?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: Yes.

(Pearson Exhibit 74 marked for identification.)

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QUESTIONS BY MR. PADGETT:

Q. Okay. I'm going to hand you what's been marked as Exhibit 74.

Is this --

MS. HUNT: Can I have a copy?

MR. PADGETT: Oh, I'm sorry.

MS. HUNT: Thank you.

QUESTIONS BY MR. PADGETT:

Q. And is exhibit -- which number is that, please?

A. 74.

Q. Is Exhibit 74 going to be introductory material about the EPA ToxCast database, followed by the specific information on acetaminophen discussed in your report there at pages 124 to 25?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: Are you asking is this specific information discussed in my report?

QUESTIONS BY MR. PADGETT:

Q. No. Would you agree that that is -- does that look familiar to you as --

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from EPA ToxCast database? At least the materials on acetaminophen?

A. Yes, it does.

Q. And the ToxCast program has acknowledged that false positive and negative hit calls are possible using their automated methods, and so they've added a processing step to assign flags or warnings about the data.

Do you understand that?

A. I do.

Q. Okay. Are there any flags or warnings referenced in the data on pages 124 to 25 of your expert report with regard to those four assays?

A. There are no flags on my expert report.

Q. Did you understand that the warnings -- do the warnings limit the conclusions that can be drawn from the results?

A. If the ToxCast algorithms flag a dose response, then it can trigger further follow-up by the computational toxicologist at the EPA to determine whether

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the curve-fitting algorithms need to be refit, whether the assay performed well, or whether the assay data are unreliable.

Q. You state there -- it's on page 124 of your report -- that the ToxCast dashboard shows APAP has potent activity for androgen receptor.

Is that -- did I read that right?

A. Yes.

Q. Did you review all of the results from the androgen receptor assays and models in the ToxCast -- EPA ToxCast database?

MS. HUNT: Object to the form of the question.

You can answer.

QUESTIONS BY MR. PADGETT:

Q. As to acetaminophen? Sorry.

A. I do not remember what I looked at. I believe that I did.

Q. Okay. So were you aware that there were 14 other androgen receptor assays that were represented as inactive?

A. There's more nuclear receptors

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beyond androgen receptor. There's --

Q. I'm --

A. -- receptor. There's -- yeah.

Q. I'm asking specifically about the androgen receptor assays.

A. I'm aware that there are other androgen receptor assays --

Q. Okay.

A. -- that are up and -- that would be up and down.

Q. Could you turn to the graph there with the date in the right-hand -- bottom right corner? Says 8/1/23, 6:04 p.m.

And which assay is this for? Is this a nuclear antagonist?

A. I assume you're asking about the one that says UPAHCLU2OSAR TIF2 nucleoli antagonist?

Q. Yes.

A. Yes.

Q. And that particular one has a flag for hit call, and it says, "Potentially confounding by overfitting. Only one concentration above baseline active."

A. I see that.

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Q. Okay. Did you see that when you were looking at the database?

A. I do not recall whether I saw that or not.

Q. Okay. But this is referring to an androgen receptor, correct?

A. This is referring to -- actually, no, it's not. It's not an androgen receptor. I misread that earlier. It's a nucleoli antagonist. Well, as it relates to the gene AR.

Q. I'm talking about the one on the graph that we're looking at.

A. Yeah, it's the same one that's the top one in the table, though.

Q. Okay.

A. The most potent one with the AC50 of .25, which is .25 micromolar or 251 nanomolar.

Q. And would you agree that this flag and the potential confounding by overfitting calls into the question of reliability of this hit?

A. It certainly requires that the toxicologist at the EPA should look more at

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this dose-response relationship and determine whether that dose response is biologically meaningful or whether one of these other concentration response curves would be better.

So the one that's fit, that gives this AC50, was what they call the winning model. So that's computational. That's why they give that dotted line. That's the winning model, and that's the log AC, that one that gives this .25 AC50.

Q. You -- sorry, go ahead.

A. So I was just going to continue on.

They give other curves. They're very, very faint in here. There's a hill curve, for instance, or a gain-loss curve. Those would render different AC 50s.

And so a toxicologist, a computational toxicologist, could look at this and determine, you know, based on this scatter plot of dose response, it might be more appropriate to not trust the computer and apply one of the other ones.

Q. You also state there on

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page 124 that it -- "the ToxCast dashboard shows that APAP has potent activity for...the nuclear receptor family in general," right?
A. Yeah, I believe I would have said that because the top two most potent assays are for two intended target families of nuclear receptor.
Q. If you could look at the graph with the bottom right date of 8/1/2023, 6:07 p.m., please.
A. Yes.
Q. And does that -- the assay for binding of the human progesterone reception?
A. Yes.
Q. And that has a flag on it, right?
A. Yes.
Q. And the flag says, quote, "Less than 50 percent efficacy," end quote, right?
A. It does.
Q. But that's not discussed in your report, correct?
A. It is not discussed in my report.
Q. You also state on page 124 that

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"the ToxCast dashboard shows that APAP has potent activity for...cytochrome P450 enzymes," correct?
MS. HUNT: Object to the form of the question.
You can answer.
QUESTIONS BY MR. PADGETT:
Q. It's on page 124 of your report.
A. Yes.
Q. And this was related to an assay at CYP1A1 induction, correct?
A. Yes.
Q. Okay. Is the CYP1A1 enzyme -- P450 enzyme typically associated with acetaminophen metabolism?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I've seen literature associated with CYP1A1 and APAP. I've seen it more in respect to aniline to APAP.
I've seen also CYP1A2 in acetaminophen.

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I think some of these assays can have some specificity problems with respect to the fact they're transcription factor reporter assays, so sometimes the CYP specificity can overlap. So it's not surprising to me to see CYP1A1 activity with respect to acetaminophen.
QUESTIONS BY MR. PADGETT:
Q. So is CYP1A1 typically associated with acetaminophen metabolism based on the literature you've seen?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: I don't know what your definition of the -- of typically is. I've seen literature associating CYP1A1 with acetaminophen.
QUESTIONS BY MR. PADGETT:
Q. In any event, this -- if you turn to the graph, 8/1/2023, for 6:09 p.m., is that the graph for the CYP1A1 induction reflected in your expert report?
A. It is reflected in my expert report.

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Oh, I'm sorry. Is the flag reflected in my expert report?
Q. Is the graph.
A. Is the graph itself or is data from the graph reflected?
Q. Yeah, the data from the graph.
A. The last entry into the table on page 125 comes from that.
Q. Okay.
A. Oh, no, I'm sorry, it isn't, actually. No, it isn't.
Q. This assay, C1P1A {sic} assay, is reflected in your report as one of the hits that you describe, right?
A. No. I don't see it.
Q. You were talking about a CYP450 assay result was among the four at pages 124 to 125; is that right?
Which one of these four is it? First, second, third or fourth? Is it the third where it says CYP1A1?
A. Oh, yeah, there it is. Thank you. It's that one.
Q. Okay. And the one that has 6:09 p.m. in the bottom right-hand --

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A. Yes.
Q. -- corner is the graph related to that assay, right?
A. It is.
Q. And that graph has a flag as well, right?
A. It does.
Q. And the flag is, quote, "noisy data," end quote; is that correct?
A. That is what it says.
Q. And what does noisy data mean?
A. It's referring to that the replicates are widespread.
Q. Could noisy data also mean meaningless or corrupt data?
A. That's not at all what that means. It just means that biology is variable. In fact, I would go on to say that this is actually beautiful data.
If you look at the lower dose range, the replicates are very tight. If you go to the higher dose range, log 1.5, then the replicates become widespread. But if you actually look at the dose-response curve, it's a beautiful sigmoidal curve. So as

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someone who is a neurotoxicologist, it's a beautiful curve. It's actually wonderful data.
Q. But it's flagged as noisy data, correct?
A. It's flagged. And so computational toxicologists want to have systems of checks and balances to make sure that the -- that the -- they have ways to have alerts. But just because flags are stimulated doesn't mean that the data are bad.
So they may very well look at this and say, oh, no, actually this looks great, and the AC50s that are generated from it are good.
Q. And the last one -- I think this is over on your table, page 125 -- is the SOX1 assay that you described; is that right?
A. Yes.
Q. And that one is in -- this exhibit is the 6:10 p.m. in the bottom right corner graph, right?
A. I see it, yes.

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Q. And that has a flag as well, right?
A. It does.
Q. And it says, "less than 50 percent efficacy, hit call potentially confounding by overfitting," right?
A. Yes.
Q. Has SOX1 activity been associated with ASD or ADHD specifically?
A. I don't know offhand if SOX1. I'm aware that SOX2 has been implicated in neurodevelopmental disorders such as ASD. I don't recall offhand if SOX1 is.
But the SOX family of transcription factors is highly implicated in such neurodevelopmental outcomes.
Q. In any event, the less than 50 percent efficacy in hit call potentially confounding by overfitting is not -- a warning flag is not referenced in your report, correct?
A. It is not.
Q. On page -- pages -- you discuss in your report, it looks like Section 11, Roman numeral XI, APAP's mechanisms of

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neurodevelopmental injury.
Do you recall that?
A. Can you tell me what page that is?
Q. Page 50.
A. Yes.
Q. Have you -- I think earlier you said you were -- you reviewed and relied upon Dr. Cabrera's report, right?
A. I read his report, and I reference it in my report.
Q. Have you reviewed Dr. Cabrera's deposition transcript?
A. I read his deposition transcript.
Q. And I'll represent to you -- I'll represent to you that Dr. Cabrera testified in his deposition that the core pathways for his opinions were oxidative stress and endocannabinoid pathways, and that for the other proposed mechanisms, at least when applying the adverse outcomes pathways, that, quote, "there would be gaps in the data that would leave a gap in the biologic plausibility that would need additional data

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to fill in those gaps."
Do you recall that?
MS. HUNT: Object to the form of the question.
You can answer, if you recall.
THE WITNESS: I don't recall that.
(Pearson Exhibit 77 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Okay. And I'll hand you what's pages 325 to 326 of Dr. Cabrera's deposition, if you want to take a look.
Can I have it back? I'll go ahead and mark it.
I'm going to hand you what's been marked as Exhibit 77. That's pages 325 to 326 of Dr. Cabrera's report {sic}.
Do you recall reading this testimony at the end of page 325 over to page 326 from Dr. Cabrera?
A. I'll need just a second to look at it.
Q. Sure.
A. It looks a little bit familiar,

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yeah.
Q. Okay. But he states with regard to mechanisms -- or pathways, biological systems -- he calls them the core pathways -- beyond oxidative stress and endocannabinoid pathways that there would -- quote, "there would be gaps in the data that would leave a gap in the biological plausibility that would need additional data to fill in those gaps," period, end quote.
Did I read that correctly?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I'm not sure you read that exactly correctly, but I think you summarized it sufficiently what was stated there.
QUESTIONS BY MR. PADGETT:
Q. Do you agree with Dr. Cabrera's statement here that beyond the endocannabinoid pathways and oxidative stress pathway, that the other mechanisms that have been -- have gaps in biological plausibility that would need additional data to fill in those gaps?

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A. I would not endorse that precisely. I do not -- I don't think that's an accurate summarization, no.
Q. And you don't think that's an accurate summarization by Dr. Cabrera, is what you're saying?
A. Correct.
Q. Okay.
A. I think there's enough -- there is sufficient information about mechanism, biological-initiating mechanisms, of damage by acetaminophen in nervous system tissues beyond oxidative stress and how that leads to neurodevelopmental injury in the developing brain, and that includes synaptic dysfunction, cellular disruption and neurodevelopmental cascades that include --
Q. Sorry.
A. Sorry.
-- that include endocrine disruption. It includes serotonergic alterations, dopaminergic dysfunction, and includes various different pathways, epigenetic disruption.
Q. You discuss in your report a

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mechanism related to AM404, correct?
A. I discuss mechanisms related to 4-Aminophenol that involve that pathway.
Q. Okay. When you say 4-Amin -- say it again?
A. I think it's 4-Aminophenol. Yeah.
Q. Is that FAAH?
A. FAAH is the enzyme that's involved in the synthesis of that particular metabolite.
Q. Okay. I think you indicate in your report a key metabolite of acetaminophen is PAP, or p-Aminophenon {sic}?
A. Sorry. p-Aminophenol, yeah.
Q. PAP, correct?
A. Yes.
Q. Okay.
A. Yeah.
Q. And that in the brain and in the presence of FAAH, PAP can conjugate with arachidonic acid to form AM404; is that correct? Is that a correct representation of your --
A. That's my recollection without

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seeing it in front of --
Q. Okay.
A. -- in front of my -- in front of me.
Q. What percentage of acetaminophen is metabolized to PAP?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I do not know the specific number. My recollection is it's a small percentage.
QUESTIONS BY MR. PADGETT:
Q. Is it more or less than the percentage of NAPQI that is formed during acetaminophen metabolism?
And if you want to look to page 8 of your report, there's a discussion of this.
A. So on the bottom of page 8, it shows a diagram that gives approximate metabolic fates of acetaminophen products.
And to answer your question specifically, it says 5 to 10 percent of acetaminophen ends up as NAPQI.

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But that's state-dependent. That depends on, you know, how much CYP2E1 there is. CYP2E1 is variable.
It also depends on how much glucuronidation or sulfation is happening to the parent molecule.
It also depends on how much parent molecule there is.
Q. Okay.
A. It also depends on how much glutathione there is, of course.
Q. And you're referring on page 8 to Figure 2, right?
A. To Figure 2, yes.
Q. Okay. And based on Figure 2, you would agree that 60 percent of acetaminophen is metabolized through glucocorn -- corn -- glucuren -- how do you say it?
A. Glucuronidation.
Q. Glucuronidation, and 30 percent through sulfation, right?
A. These are approximate numbers. There are species differences. There's developmental differences. These are --

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again, it's a snapshot to give approximate -- approximations, but they can be helpful as a -- as an approximation.
Q. Okay. But that's what -- those numbers are what's reflected in Figure 2 of your -- page 8 of your report, right?
A. Yes.
Q. Okay. And the metabolite -- metabolism pathway for -- to NAPQI is APAP conjugate -- is conju -- is bound with CYP2E1 to create NAP -- NAPQI, right?
A. CYP2E1 oxidizes acetaminophen to NAPQI, yes.
Q. Okay. And then GSH, essentially an antioxidant that converts NAPQI to a harmless metabolite that's excreted in the urine, right?
A. That's an okay-enough summarization, yes.
Q. Okay. And some acetaminophen is excreted as is -- in urine in unconjugated form, right?
A. Very little.
Q. Okay. Is it about 5 percent?
A. I don't know the exact number,

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but most of it is processed.
Q. PAP is not on this graphic in Figure 2, correct?
A. It is not.
Q. And I don't believe I saw this in any study cited in your report, but correct me if I'm wrong, but are there any studies that have measured AM404 in the human embryotic fetal brain?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I do not know.
QUESTIONS BY MR. PADGETT:
Q. Okay. In your opinion, is one molecule of AM404 in the fetal brain sufficient to cause ASD?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I do not have any knowledge of how much AM404 would be required to cause ASD.
QUESTIONS BY MR. PADGETT:
Q. And same question for ADHD. Is one molecule of AM404 in the fetal brain

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sufficient to cause ADHD?
MS. HUNT: Same objection.
THE WITNESS: Asking a question about an individual molecule causing a complex human disease is, I think, indicative of how -- why something like a weight of evidence is necessary, because that's just not how disease risk works. We're dealing -- again, we're dealing with, like, complex, pleiotropic disease.
It's -- so to more directly answer your question, I cannot answer that question. It's not possible to answer that question.
QUESTIONS BY MR. PADGETT:
Q. Okay. And to your point about a weight of evidence, are you aware of any studies that have measured AM404 in human adults?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I have not reviewed the literature about whether

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AM404 has been measured in human biospecimens. So I don't know.
QUESTIONS BY MR. PADGETT:
Q. And is it your opinion that AM404 increases anandamide and that this increase of anandamide disrupts the endocannabinoid system?
A. My understanding is that AM404 is involved in endocannabinoid signaling, and disruption to the endocannabinoid signaling system is -- can perturb neurodevelopment.
Q. And do you have any understanding of the level at which a decrease of AM404 would sufficiently perturb the endocannabinoid system to result in an increased risk of ASD?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: That is not my expertise. I'm not a person who is trained in the dosimetry of AM404 in the human brain to determine what the levels are that are required to lead to a human disorder. That's outside of my training.

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QUESTIONS BY MR. PADGETT:
Q. And you said it would lead to a human disorder. So the same response would be true with regard to ADHD, correct?
A. Same answer.
Q. You assert on page 63 of your report that it is well-accepted that endocannabinoid disruption during pregnancy should be avoided, and there you cite ACOG, right?
A. Yes.
Q. So there you do, in fact, believe that ACOG is a valid source of medical opinion, correct?
MS. HUNT: Object to the form of the question.
You may answer.
THE WITNESS: Citing a particular reference means that that particular reference is what I'm referring to to support that statement.
(Pearson Exhibit 75 marked for identification.)

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QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit Number 75. Is that the source that you're referring to with regard to your citation to ACOG?
A. I believe it is. Yes.
Q. And that is a flyer from ACOG warning about using marijuana while pregnant, correct?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I'm sorry. The question is whether this is a flyer?
QUESTIONS BY MR. PADGETT:
Q. Is that a -- is that -- will you confirm that Exhibit 78 is an ACOG flyer advising against the use of marijuana during pregnancy? Correct?
A. This is a -- this is a couple of documents from ACOG that discuss the topic of marijuana in pregnancy.
Q. And the bulletin that's Exhibit 78, the ACOG bulletin, states, quote, "Research is limited on the forms of

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marijuana use during pregnancy because all of the possible harms are not fully known. ACOG recommends that anyone who is pregnant, planning to get pregnant or breastfeeding not use marijuana," period, end quote.

Did I read that correctly?

A. You did.

Q. And THC use during pregnancy is discouraged because research is limited on the harms of marijuana use during pregnancy, and all of the possible harms are not fully known, correct?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: You were asking me about THC use? I didn't understand the question.

MR. PADGETT: Can you read it back, please?

Strike that.

QUESTIONS BY MR. PADGETT:

Q. According to this ACOG bulletin, THC use during pregnancy is discouraged because research is limited on the harms of marijuana use during pregnancy

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and all of the possible harms are not fully known, right?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: I want to make sure I understand the question.

So you're asking whether ACOG is recommending that pregnant people don't use THC while pregnant because all of the harms aren't known? And you're asking me to say yes or no to that?

QUESTIONS BY MR. PADGETT:

Q. Is that your understanding? That's my question.

A. I don't -- I wouldn't fully agree with that, because as they're saying here, they're saying possible effects on your fetus - disruption of brain development before birth, smaller size at birth. They're listing many, many effects.

So it's not just because the possible effects aren't known. I can't endorse that particular response to the affirmative as you phrased the question.

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Q. Do you believe it's appropriate to extrapolate from the effects of one endocannabinoid compound to make a causation argument about another compound acting on an endocannabinoid system?

A. I think -- I think it's -- I think that knowing that a particular ligand of receptors affecting neurodevelopment can tell you that. You have to be careful with other known ligands to those receptors when a full safety profile of that particular chemical in question has not been performed.

Q. And we're talking about ASD or ADHD. Wouldn't you need to be specific as to the particular neurochemicals or transmitters that have been linked with ASD in terms of perturbing of the endocannabinoid system?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: So with ASD and ADHD -- so we're talking about now two different disorders, endocannabinoids and now neurotransmitters. So now I'm a little bit confused about what specifically you're asking me.

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So specificity about which chemicals that act as ligands for the endocannabinoid system?

QUESTIONS BY MR. PADGETT:

Q. Yes.

A. Or neurotransmitters?

So you're not asking me about neurotransmitters?

Q. Not right now.

A. Okay. So, no.

Q. Same question about neurotransmitters.

Don't you need to know the particular neurotransmitters that have been linked with ASD in terms of perturbing of the endocannabinoid system in making a causal assessment?

A. I'm not certain I understand what you mean with respect to endocannabinoids and now neurotransmitters.

Q. What specific neurochemicals have been identified as perturbing the endocannabinoid system as cause -- as specifically causing ASD?

MS. HUNT: Object to form.

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You can answer.
THE WITNESS: I'm really having a hard time understanding what you're asking me.
So specificity about neurotransmitters that are involved in ASD and ADHD and how that relates to endocannabinoids?
Look, I think what we're discussing here is the involvement of the endocannabinoid system and whether acetaminophen is perturbing endocannabinoid system.
If we're talking about the endocannabinoid system as a mechanism by which acetaminophen is disturbing neurodevelopment, what that has to do with neurotransmitters, serotonin, dopamine, you know, norepinephrine, et cetera, I don't see the link here, like what -- how I'm supposed to answer your question.
QUESTIONS BY MR. PADGETT:
Q. Let me ask you this way.
Do you -- can you identify a

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single study that suggests or reports that AM404 has neurodevelopmental effects, including the development of ASD or ADHD?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: If AM404 has neurodevelopmental effects.
I do not recall studies that specifically look at AM404 and directly linking to neurodevelopmental effects in humans.
MR. PADGETT: We've been going over an hour. Do you want to take a break?
MS. HUNT: Sounds good to me.
VIDEOGRAPHER: The time right now is 2:41 p.m., and we're off the record.
(Off the record at 2:41 p.m.)
VIDEOGRAPHER: The time right now is 3:02 p.m., and we're back on the record.
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, I'm going to take

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you all the way back to page 10 of your amended expert report.
You have a statement there that says that a fetus has, quote, "Less ability to detoxify NAPQI," period, end quote.
It's at the very -- towards the very bottom of the page.
Do you see that?
A. Yes.
Q. Okay. Aside from the statement about lower glucuronidation capacity, do you have any other studies supporting the proposition that fetuses have less ability to detoxify NAPQI?
A. It's well-understood that the hepatic -- the liver enzymes and liver activity of embryos and fetuses are limited, so it's not until late term and postnatal that the activity of the liver is fully on board. So the fetus is relying on maternal detoxification to some degree.
Q. Okay.
A. And I don't know exactly where I have that cited in here, but that's a well-understood metabolic and toxicological

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phenomenon.
Q. What about levels of GSH in the fetal brain, do you have any understanding of the levels of the GSH that are present in the fetal brain shown by any scientific research?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: There's the study that we discussed earlier that had some limitations in terms of controls but nevertheless gave some information on this. And that is Beck, in rat, shows us that low weight files are reduced, that glutathione was reduced in the fetal brain relative to other tissues, and that acetaminophen changes that.
And so there's developmental dynamics of glutathione levels in fetal tissues and in fetal brain, and those change over time.
QUESTIONS BY MR. PADGETT:
Q. But you're talking about rat --
A. I am talking about rat.
Q. Okay. What about studies about

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GSH in the fetal human brain?
MS. HUNT: Object to the form of the question.
You can answer.
QUESTIONS BY MR. PADGETT:
Q. Any do you have -- are you aware of any studies looking at that?
A. Off the top of my head, I'm not sure if the glutathione in human embryos or fetuses has been measured. It may very well have.
Q. I'm going to hand you what has been previously marked as Exhibit 43. It was in -- from Dr. Louie's deposition. It's got a chicken scratch from Dr. Louie on it.
Have you -- have you read this article before?
A. Let me look at the figures and see if I recognize it.
I don't know if I relied on this or looked at it or not. I don't recognize it. But I may have.
Q. I do not believe it was on your list of materials, but you also don't recall looking at it within the past month or two?

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A. I do not recall looking at it, no.
Q. Okay. And this article reports on table -- in specifically Table 2, GSH levels in the fetal brain and liver of -- as of 13 weeks, correct?
A. I see that in Table 2.
Q. Okay. And you indicated earlier that acetaminophen -- you said that the -- that the P -- we rely on the mother's metabolism in the liver to deal with NAPQI; is that right?
A. I did not say that.
Q. Okay. What did you mean? You were talking about it earlier.
A. I was saying that the liver on the whole is not fully functional in a developing embryo or fetus, and that some of the detoxification of circulating xenobiotics would require hepatic function of the mother.
Q. Okay. At least here, brain GSH shows 80 nanomole per milligrams systolic protein for GSH, correct?
A. Nanograms per milligram, yes.
Q. Okay. And have you reviewed --

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strike that.
I'm going to hand you what's been marked previously in Dr. Louie's deposition as Exhibit 40, ask do you recognize that study?
A. I do not recognize this study just based on the title page.
Q. If you turn to Table 2 in Figure B of this -- and this is the Dutheil 2009 study, correct?
A. Yes.
Q. And this is looking at CYP2E1 mRNA expression in the human brain and in the liver and various other -- specifically in the liver and various parts of the human brain, correct?
MS. HUNT: I would just -- sorry. I object to the form.
You can answer, if you have a chance.
THE WITNESS: Which figure are you wanting to --
QUESTIONS BY MR. PADGETT:
Q. Table 2.
A. Table 2. Okay. I'm looking at

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Table 2.
Q. Do you see that with regard to the liver, the expression of CYP2E1 mRNA compared to the brain is 1,300-plus times larger --
MS. HUNT: Object to the form.
QUESTIONS BY MR. PADGETT:
Q. -- in the liver than in the brain?
MS. HUNT: Sorry.
Object to the form of the question.
You may answer.
QUESTIONS BY MR. PADGETT:
Q. More than a thousand times higher, correct?
MS. HUNT: Same objection.
THE WITNESS: So I've not looked at the study before, but if you're asking me the question whether the number 550,000 is larger than 413, a thousand times larger, the answer to that would be yes.
QUESTIONS BY MR. PADGETT:
Q. Have you reviewed Dr. McGill's

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report in this case?
A. I did not read his full report, but I looked over parts of it.
Q. Did you review the parts of it related to the levels of CYP2E1 as compared to GSH in the human and rodent brains compared to the liver?
MS. HUNT: Object to the form of the question.
Answer, if you can.
THE WITNESS: I did not review all of that. Part of what I read I did not feel was accurate, so I didn't spend the precious time that I had looking at the rest of it.
QUESTIONS BY MR. PADGETT:
Q. Which part did you feel was not accurate?
A. So various parts of it I did not feel were accurate. I can't quote to you which parts of it.
But just to give you an example, I can already tell you issues with the interpretation of this. This is giving you transcript levels, which is not

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sufficient here.
I don't know whether they have controlled for, for instance, the million map reads. I don't know if they're controlling for the size of the -- I don't know if they're controlling here for the protein levels.
This is just transcripts. There's a number of issues here of just relying on only transcript level. So making these tissue-level comparisons is insufficient with -- in terms of understanding the abundance of the enzyme.
It would be better to support this with -- or it would be helpful to support this with either immunolabeling, Western Blot, something of the sort, proteomics, if one was to try to make the conclusion that -- you know, the relative abundance of the enzyme. This is just message.
Q. Are you aware of any studies that show that in the fetal brain the levels of GSH are not abundant enough to take care of NAPQI that would be created by whatever

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levels of CYP2E1 are in the fetal brain?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: Under what circumstances? Under any circumstance or under the circumstances of acetaminophen exposure?
QUESTIONS BY MR. PADGETT:
Q. Under the circumstances of acetaminophen exposure.
A. Baker, et al., 2023.
Q. Can you say that again?
A. In our own study, Baker, et al., 2023, demonstrates that.
Q. And what does that demonstrate?
A. It demonstrates that there's oxidative stress in the brain. If there's oxidative stress in the brain, it demonstrates that the antioxidant systems such as glutathione are insufficient to deal with the prooxidant imbalance. As do any of the other studies that show that there's elevations in prooxidants or oxidative stress.

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In other words, you don't have to be able to measure glutathione. You don't necessarily have to measure CYP2E1. You don't necessarily have to measure or prove that the glutathione is insufficient when you can show that there's oxidative damage.
When there's evidence of oxidative damage, you don't have to measure the CYP2E1. You don't have to measure the glutathione. Or you don't have to measure the radical itself, which is a very difficult thing to do.
There's plenty of studies that show the damage of the radical and the insufficiency of the antioxidant in the face of the acetaminophen exposure.
Q. Are you aware of any -- strike that.
Have you -- are you familiar with the Human Protein Atlas?
A. I'm aware of the Human Protein Atlas, yes.
Q. Have you reviewed levels of CYP2E1 protein expression and mRNA expression for CYP2E1 in the Human Atlas?

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A. Yes. In my expert report, I provide data -- I believe it's from the Human Protein Atlas -- showing brain levels of CYP2E1 to give an example of how in various brain regions the expression can vary but that it is expressed.

Oh, that's the BrainSpan. Excuse me. It's not the Human Protein Atlas, but it's BrainSpan. Just a similar type of a database, though.

Q. Okay.

A. I'll point something out -- else that I believe is relevant to that as well.

If you compare something like the liver to the brain, the relative abundance of something like CYP2E1 shouldn't be compared on the same scale because, for instance, in the liver, if you have lower levels of an antioxidant in one versus the other, or lower levels of an enzyme that converts a drug, a parent drug, to a prooxidant, even low levels of that enzyme can be more harmful in an organ that doesn't regenerate, like the brain, versus a tissue,

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like the liver, that can regenerate.

You can remove 90 percent of your liver, and it can regenerate. You can damage a very small part of your brain, and it doesn't regenerate.

So the relevance of this being is that if you damage neurons in your brain and they die, or they become comprised, they cannot regenerate in the same way that your liver can.

So the liver has different mechanisms to deal with damage. So hepatocytes in the liver, if they're damaged, if there's DNA damage, if there's oxidative stress, they prefer to just die and replace themselves.

Your brain cannot and does not do that in the same way.

So the antioxidant systems are different. The way that they respond to damage is different.

So small amounts of damage, small amount of prooxidants in discrete areas in the brain matter, and the impacts of that are much, much larger.

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So saying that there's -- oh, there's smaller amounts of CYP2E1 versus the liver, it's not a fair comparison.

Q. Can you identify a study that quantifies the level of imbalance needed between GSH and oxidative stress in the fetal brain to cause ASD or ADHD?

MS. HUNT: Object to form.

You can answer.

THE WITNESS: That sort of a study is not necessary when you can just introduce the perturbagen, agent, drug in question and then look if you have relevant outcomes.

It's not necessary to sort of do this sort of mathematical hypothetical and say, what's the relative amount, when you can actually just do the experiment. Does the test agent elicit the effect.

QUESTIONS BY MR. PADGETT:

Q. My question -- my question is, can you identify a study that quantifies the level of imbalance needed between GSH and oxidative stress in the fetal brain to cause

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ASD or ADHD?

MS. HUNT: Same objection.

QUESTIONS BY MR. PADGETT:

Q. I understand you're saying you don't need that, but I'm asking, do you -- can you identify one that does that?

A. Can I identify a study that compares the amount of imbalance between GSH and oxidative stress that leads to ADHD or ASD?

Q. Yes.

A. That's not how scientists approach these problems.

Scientists approach these problems by sort of a scientific method by saying, there's the -- there's a question, does this particular substance cause this effect; what's our hypothesis; what's our prediction; how can we set up the experiment and look at it.

I don't think I can answer your question the way that it's phrased.

Q. My question is, can you identify a study that compares the amount of imbalance between GSH and oxidative stress

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that leads to ADHD or ASD.
If your position is that my question is irrelevant, fine.
But can you identify such a study?
MS. HUNT: Objection. Asked and answered.
You can answer again.
THE WITNESS: Well, I'll try to make it simpler.
As my testimony from earlier in the day stated, the reason why the question would be irrelevant is because we're talking about health outcomes that are highly heterogeneous, that do not involve a singular pathology, a singular tumor, a singular, you know, break in a bone or something like that that you could point to to say that, okay, this is the thing that leads to the behavioral outcome that you could say, oh, that's what we can pinpoint, say that is the individual thing, and then create that calculation.

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QUESTIONS BY MR. PADGETT:
Q. Baker 2023, the behavioral studies there did not show any changes consistent with the ADHD model of attention deficits, correct?
MS. HUNT: Objection. Misstates evidence.
You can answer.
THE WITNESS: So --
MR. PADGETT: Object to form is -- pursuant to the order.
MS. HUNT: Yeah, you should have tell Ali Brown that for her next deposition.
QUESTIONS BY MR. PADGETT:
Q. Go ahead.
A. In the Baker 2023 paper, we showed disruptions to motor activation. We showed disturbances to pup ultrasonic vocalizations, which is a neurodevelopmental phenotype that's early in development. And we showed suggestive, perhaps behavioral -- behaviorally relevant but not statistically significant changes in impulsive, relevant and attentional -- attentioned -- sorry,

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attention in the five-choice serial-reaction test in mice.
Q. But not statistically significant?
A. Not statistically significant.
Q. Okay.
A. And multiple different endocrine oxidative stress, DNA-damage-related changes in the brains of the mice that were prenatally exposed.
Q. Can we agree that studies of increased oxidative stress in individuals with ASD or ADHD involve measurements taken years after those individuals were born? Correct?
A. Some studies that look at individuals diagnosed with ASD or ADHD, those biomarker studies were collected from individuals after diagnosis. Not all of them.
Q. Carey '22 was a study that looked at oxidative biomarkers during gestation, correct?
A. I don't have that study in front of me, so I can't speak to it.

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(Pearson Exhibit 78 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, I'm going to hand you what's been marked as Exhibit 78.
Is that -- first of all, are you familiar with the Carey '22 -- 2022 study?
A. I'm not sure --
Q. Actually, the Carey -- now the Carey -- that was the online version in 2022.
Actually, are you familiar with the published 2023 Carey study?
A. I don't recall looking at the study.
Q. So you have not reviewed this study?
A. I do not recall having looked at this study, no.
Q. You want to take a moment to review it?
A. Yeah. If I could have just a couple of minutes, that would be great.
Okay. I feel like I have a quick -- a quick glance of it, have a feel

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for it.
Q. Can you turn to page 2976?
A. Okay.
Q. Left column, about halfway down.
A. Yes.
Q. You see the word -- the sentence that starts "However"?
A. You said left column halfway down or right column?
Q. Left column, halfway down.
A. Yes.
Q. And it says, quote, "However, retrospective studies in children already diagnosed with ASD cannot provide evidence as to whether oxidative stress differences are a cause or a consequence of ASD," period, end quote.
Did I read that right?
A. You did.
Q. Do you agree with that?
A. Those studies have limitations in that regard, certainly.
Q. When you say "in that regard," you're -- you mean with regard to determining

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etiology during conception versus as a consequence of ASD?
A. I would in general agree with their statement, is what I'm saying.
Q. And would you agree that the same is true with regard to whether oxidative stress differences are a cause or a consequence of ADHD? Differences seen in ADHD patients?
A. I think this statement would apply to that as well.
This is why we need preclinical studies as well.
Q. And the Carey 2023 study that is Exhibit 78 looked at oxidative stress biomarkers during gestation, correct?
A. Yes.
Q. Okay. And it determined that increased oxidative stress during gestation did not have -- during late pregnancy did not show a relationship with increased risk of autism clinical diagnoses, correct?
MS. HUNT: Object to the form of the question.
You can answer.

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THE WITNESS: I wouldn't agree with that. The abstract says, "Results from this cohort with increased risk for autism do not support a strong relationship between oxidative stress in late pregnancy and autism-related outcomes."
They do not say there's no relationship.
QUESTIONS BY MR. PADGETT:
Q. There was not a statistically significant relationship of such an association, agreed?
A. They are underpowered, so they are not able to fully state that with confidence.
Q. Where do they state that they're underpowered?
A. I didn't read the whole article, but I'm looking at their sample size, so...
They have a sample size of 30 in the autism group.
Q. Are you aware of any other study looking at gestational exposure and

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increased oxidative stress during gestation and clinical -- and any association with clinical diagnoses of autism spectrum disorder?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: So your question is, am I aware of any other studies that look at oxidative stress biomarkers and autism or ADHD outcomes?
QUESTIONS BY MR. PADGETT:
Q. Autism clinical diagnosis outcomes.
A. Yes. There is a study that looked at hydroxyguanosine in cord blood, and that is by -- oh, who did that study?
Q. Are you thinking of the Anand study?
A. Anand. Thank you.
Q. That was ADHD, though, right?
A. That was ADHD, yes. That was not autism.
And there's multiple postmortem

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brain tissue studies looking at oxidative stress markers and autism.
Q. That goes back to the consequence or causation issue that we discussed earlier, right?
A. It would.
Q. Anand -- are you referring to Anand 2021?
(Pearson Exhibit 79 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit 79.
Is this the Anand 2021 study that you were referring to?
A. It is.
Q. And this examined cord blood and a specific -- well, you -- yeah, you discuss this at page 52 of your report.
You state that it showed, "high concentrations of acetaminophen have been shown to be associated with higher levels of a specific biomarker of oxidative stress and higher odds of ADHD."
Is that -- is that correct?

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A. I'm just going to go to that page in my report real quick.
Yes.
Q. And it states that the children with cord acetaminophen in greater than 50th percentile -- so that's in the top half -- had higher odds of ADHD when the -- when the cord 8-hydroxydeoxyguanosine levels were less than or equal to 50th percentile.
Is that right?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: What this study found was that the biomarker was linearly associated with ADHD traits when you looked at the top half of the distribution of the biomarker.
QUESTIONS BY MR. PADGETT:
Q. Would you agree that cord blood only provides a snapshot of fetal metabolism?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: Would I agree that cord blood only provides a

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snapshot of fetal metabolism?
So cord blood -- I would agree that cord blood provides fetal -- a window into fetal metabolism.
If you're asking whether it's only representing a time point of a window of gestation, that would be accurate.
QUESTIONS BY MR. PADGETT:
Q. Yeah.
And that window is right around the time of delivery?
A. It represents a window from the time -- from the -- that reflects a limited time from the birth window.
Q. And based on the half-life of acetaminophen in the human body, that time window would be no more than a day or two within the date of delivery, correct?
A. I think the actual time that it represents could represent longer than what's known as the typical half-life of acetaminophen in non-gestating individual -- like a nonfetal condition, but it's not going to be -- it's not going to be much longer

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than that, certainly.
Q. Okay. You state at page 53 of your report that "given the early life neuroinflammatory etiology of ASD and ADHD, any stressor that can cause oxidative stress or" -- "and/or inflammatory signaling has a potential to trigger the cellular and synaptic changes that underline" -- "underlie ADHD."
Did I read that correctly?
A. Let me get to where it says that.
Is that towards the top or -- you said that's on 53?
Q. Yes.
A. I don't see exactly where it says that. Maybe you can help me find that.
MS. HUNT: I think your page numbers may be off.
MR. PADGETT: Yeah.
MS. HUNT: Sorry.
MR. PADGETT: Well, I'm looking at your -- yes.
QUESTIONS BY MR. PADGETT:
Q. Sorry. Page 54.

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A. Okay.
Q. It's the end of -- under number 3, Oxidative Stress and Inflammation.
"Given the early life and neuroinflammatory etiology of ASD and ADHD, any stressor that can cause oxidative stress and/or inflammatory signaling has the potential to trigger the cellular and synaptic tinges that underlie ADHD."
Did I read that right?
A. You did.
Q. Okay. And page 12 of Anand actually acknowledges that cord plasma -- and this is at page 12 -- measurements of analytes collected at birth may reflect only a snapshot of fetal metabolism. And it's difficult to draw temporal conclusions.
Do you see that?
A. I see that, yeah.
Q. Okay. And given that acknowledgement in Anand that cord blood measurements are a snapshot and, as you discuss, right around labor and delivery, how can you exclude higher use of APAP due to a more painful or complicated labor and

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delivery as being responsible for why there may have been more APAP used right around the time of delivery?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: I mean, I really -- generally, I really appreciate it when observational epi folks acknowledge -- fully acknowledge the limitations of their studies, just like us experimentalists need to do.
I mean, this is, again, why it's incredibly important why we look at the epidemiology alongside the preclinical studies.
The preclinical studies don't suffer from that. The mice don't take medication at the end of term pregnancy for any reason. So we don't have confounding.
So if epidemiology existed in isolation, these types of concerns would remain, and they would not be backed by all the preclinical studies

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showing and bolstering the causality. If we only had preclinical studies, we'd be facing the limitations of preclinical studies in isolation.
We are fortunate that we have all of these things together that bolster one another.
So in other words, they're right that there are limitations of the fact that there is this window, that their analytical approaches are measuring a relatively small window because of the half-life.
QUESTIONS BY MR. PADGETT:
Q. Would you agree that pain could be one of the, quote, "anti-stressors," end quote, that could cause oxidative stress and/or inflammatory signaling towards the end of a -- during labor or delivery?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: I'm not aware that pain causes hydroxyguanosine radicals in brain tissue.
(Pearson Exhibit 80 marked for

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identification.)
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, I'm going to hand you what's been marked as Exhibit 80.
Do you recognize that study?
A. This looks like a review article, not a study.
Q. Sorry.
Do you recognize that review article, Nicolini 2017? Have you reviewed that?
A. I may have. I do not recall.
(Pearson Exhibit 81 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit 81 to your deposition and ask, do you recognize that review article, Kirkland 2021?
A. I have looked at this before.
Q. You have?
A. I have.
Q. And do you have any -- do you take issue with any of the conclusions in this article?

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MS. HUNT: Object to the form of the question.
THE WITNESS: I would -- I would have to go through it in detail again to -- because I don't remember if I have any formal issues with anything that's raised in this.
QUESTIONS BY MR. PADGETT:
Q. Can you turn to page 57 of your amended report?
A. Okay.
Q. Do you see the part where you're talking about, there at the bottom of page 57, DNA damage being implicated in the development and progression of neurodegenerative disease like ALS, Parkinson's and Huntington's disease?
A. Yes.
Q. Are you -- are you analogizing ASD and ADHD to neurodegenerative diseases with average ages of onset of 55 for ALS, 60 for Parkinson's, and over 65 for Alzheimer's?
MS. HUNT: Object to the form of the question.
You can answer.

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THE WITNESS: Are you asking me if I'm drawing an analogy between ASD and ADHD and these neurodegenerative diseases?
QUESTIONS BY MR. PADGETT:
Q. Yes.
A. I am not saying that these are the same thing, but I'm saying that these are other neurological conditions, which ASD and ADHD are. They're not neurological disorders that have DNA damage as components to them.
Q. Okay. Your report discusses cell death and apoptosis, right?
A. Yes.
Q. Okay. What studies support that acetaminophen at therapeutic doses causes apoptosis in human brain cells?
A. Let me find it. There is a study in the -- in the -- in the in vitro section.
Labba, et al., is one.
Sorry, that's -- may not -- that's not apoptosis, per se. That's cell death, but...
Q. And while you're looking there,

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I'm talking at therapeutic human doses.
MS. HUNT: Object to the form of the question.
THE WITNESS: Yeah. So the Posadas, et al. -- no, sorry, that's cortical neurons from rats, so that's not human cells.
I suppose the most relevant is the Labba, et al., which is cell line -- cell line study.
QUESTIONS BY MR. PADGETT:
Q. The Labba, et al., 2022, is that what you're referring to?
A. Yes.
Q. That study involved the use of chicken granule cell neurons and human cancer cells, right?
A. Yes.
Q. And regardless of the cell types involved, that study involved 72 hours of steady concentrations ranging from 200 micromolar to 1600 micromolar.
A. 100 to 1600, yes.
Q. And were there effects seen at 100 micromolar? Apoptosis, specifically?

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A. Let me look at what they found here. Cell death was found only at the higher dose range.
Q. And that's -- was that 1600 or was there -- was it seen below that?
A. It was -- I think it was -- I don't recall if it was at the 1600 or if it was at the 800, but it was -- it was not at the lower doses, which would have been more physiologically relevant.
Q. And is 72 hours of steady concentration of acetaminophen biologically relevant to human dosing of acetaminophen?
A. I think that can be very biologically relevant.
Q. Staying at a steady concentration for 72 hours from a single dose is biologically relevant?
MS. HUNT: Objection. Form.
You can answer.
THE WITNESS: I already answered the question.
This is a drug that can be given every four to six hours.

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QUESTIONS BY MR. PADGETT:
Q. Is 72 hours' steady concentration at 800 micromolar to 1600 micromolar consistent with therapeutic dosing of acetaminophen?
A. That latter part is not what I was saying, but I -- at 800 micromolar, I don't necessarily think that's physiologically relevant.
The lower end of the dosing range I think is physiologically relevant, but steady-state in an in vitro system can be physiologically relevant.
Q. But 72 hours of steady concentrations below 1800 micromolar did not show any apoptosis?
A. In that study, no.
Q. Do you rely on Posadas 2010 to support that acetaminophen causes apoptosis in human brain cells at therapeutic doses?
A. No.
Q. You have a subsection called Epigenetics. Page 60. Do you see that in your report?
A. Epigenetic Changes, yes.

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Q. Are you relying on Dr. Baccarelli's opinions with regard to epigenetics, or have you reached your own conclusions with regard to epigenetics?
You referenced Dr. Baccarelli's report here, right?
A. Yes, because Dr. Baccarelli -- so I do not review the observational epidemiological literature, but Dr. Baccarelli is an environmental epigeneticist and epidemiologist, so I reviewed his summary of that literature, and so I refer to that here.
Q. Did you do your own independent analysis of that literature to reach your own opinion, if any, with regard to epigenetics?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: So I've seen that literature, and I'm familiar with it, but I do not use it in my weight of evidence analysis.
I focus my weight of evidence analysis on the preclinical

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literature.
QUESTIONS BY MR. PADGETT:
Q. For example, you are not relying on the Gervin 2017 study for your weight of analysis opinions in this case?
A. Gervin -- the Gervin study, I assume, is a human biospecimen study looking at epigenetics.
Q. Correct.
A. So then I would not have included it in my weight of evidence analysis.
Q. Okay. Did you rely on it in any way in reaching your opinions in this case?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: So to the extent that the epidemiological information and evidence is part of the overall scope of this topic, it's important to the general context.
But again, in forming my opinions for the weight of evidence analysis, I limited the information to

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the scope of the preclinical literature.
But I have a background in epigenetics, and so I'm interested in this topic as well, but I focus on preclinical literature.
QUESTIONS BY MR. PADGETT:
Q. In light of your interest in epigenetics and your background, did you review the Olstad 2020 study?
A. Not in detail.
Q. Did you take the Olstad 2023 study and its findings into account in reaching your opinions in this case?
A. The weight of evidence analysis that I conducted is focused on the preclinical literature.
Q. I guess I'm a little bit confused by your earlier testimony, so I'm trying to clear it up, at least in my mind.
In reaching your opinions in this case, did you rely on Gervin 2017 as a basis for them?
A. So I do not rely on the observational epidemiological literature to

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form my opinion in this case.
MR. PADGETT: Take another break? I'm kind of at a breaking point.
MS. HUNT: Okay.
VIDEOGRAPHER: The time right now is 3:56 p.m., and we're off the record.
(Off the record at 3:56 p.m.)
VIDEOGRAPHER: The time right now is 4:17 p.m., and we're back on the record.
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, if you turn to page 63 of your report, your amended report, you discuss brain neuratrophic factors as a mechanism.
And you state there that evidence in the case demonstrates that BN -- BDNF in the developing brain is altered by APAP exposure, and then you cite Blecharz-Klin 2018, Lalert 2023 and Viberg 2014, correct?
A. That's what it says.
Q. Have animal studies on APAP

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reported consistent findings on altered BDNF?
MS. HUNT: Object to the form.
You can answer.
THE WITNESS: What is your definition of consistent?
QUESTIONS BY MR. PADGETT:
Q. You see a change in one area of the brain, for example, and it's replicated in another area of the brain.
MS. HUNT: Object to form.
You can answer.
THE WITNESS: So what's being reviewed here is that all these studies see disruptions to BDNF in general. It doesn't necessarily mean that all the studies show the same exact change, necessarily, or all the same brain regions, but these studies support that BDNF is disrupted by acetaminophen.
QUESTIONS BY MR. PADGETT:
Q. Is it your opinion that you do not need consistency across studies assessing the same parameter in order to make a reliable conclusion regarding biologic

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plausibility?
MS. HUNT: Object to form.
You can answer.
THE WITNESS: So you're asking whether I -- it's my assertion that studies do not need to have consistency across studies. It's not necessarily my assertion.
What I'm asserting is that the particular outcome variables in studies, the directionality of the outcome variables in the studies, can be bivalent. So under certain circumstances, the directionality of the findings can be perturbed in either direction. That doesn't mean the study's relevance -- the relevance of those findings aren't important.
In general, though, concordance is important when weighing the outcomes of studies in a systematic review.
(Pearson Exhibits 82 and 83 marked for identification.)

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QUESTIONS BY MR. PADGETT:
Q. I'm going to hand you what's been marked as Exhibit 82. Is that Viberg -- the Viberg 2014 study article?
A. Yes.
Q. Going to hand you what's been marked as Exhibit 83.
Is that the Blecharz-Klin 2018 article?
A. Yes.
(Pearson Exhibit 84 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Handing you what's been marked as Exhibit 84.
Is that the Philippot 2018 article discussed in your report?
A. This is Philippot 2018, yes.
(Pearson Exhibit 85 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm handing you what's been marked as Exhibit 85.
Is this -- and you may need to look at your report for this one. Is this

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Blecharz-Klin 2015 B referenced in your report?
A. Yes.
(Pearson Exhibit 86 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. I'm now handing you what's been marked as Exhibit 86.
Is this the Blecharz-Klin 2016 report?
A. Yes.
(Pearson Exhibit 87 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Now handing you what's been marked as Exhibit 87.
Is this the Blecharz-Klin 2019 study article?
A. Yes.
Q. Dr. Baccarelli {sic}, do you -- is -- sorry.
Dr. Pearson, is Dr. Baccarelli, is he considered your superior at Columbia?
A. He's my department chair.
Q. Is he -- would you characterize

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him as your boss at Columbia?
A. He's -- yeah.
Q. Okay.
A. Yeah, that's fair.
Q. Have you disclosed to Columbia University that you're participating as a paid expert witness in this litigation?
A. I have.
Q. Do you know whether Dr. Baccarelli connected you with plaintiffs' counsel? Or connected plaintiffs' counsel to you?
MS. HUNT: Object to the form of the question.
THE WITNESS: I do not know.
QUESTIONS BY MR. PADGETT:
Q. If you could turn to pages 64 to 65 of your report, your amended report.
You state there that -- it's a section entitled "Effects on Serotonergic Signaling," and you state that there -- quote, "There is also evidence that APAP may affect normal serotonergic signaling and function in the brain during neurodevelopment," end quote.

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Is it your opinion -- is it your opinion that APAP affects normal serotonergic signaling and function in the brain during neurodevelopment?
A. It is among my opinion that the mechanism of action that acetaminophen influences in the brain is the serotonergic system, and that's been supported in the literature.
Q. And then at page 65, you indicate that animal studies show that APAP has an effect on serotonin function and signaling in the prefrontal cortex, and you start -- you cite Blecharz-Klin 2017.
Do you see that?
A. I see that.
Q. Was that finding consistent across the other Blecharz-Klin studies that looked at, for example, 5-HT signaling pathways?
Strike that.
Is 5-HT signaling pathway related to the serotonin function?
A. 5-HT is serotonin.
Q. Okay. So was that finding in

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2017 consistent across the other Blecharz-Klin studies?
A. The other Blecharz-Klin studies looked at other regions of the brain.
Q. All right. And other regions of the brain show no changes in 5-HT signaling in, for example, Blecharz-Klin 2015 B, 2016 and 2019?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: So we would -- we would have to look at those studies one by one if we want to evaluate what the serotonin effects were.
QUESTIONS BY MR. PADGETT:
Q. Sure. Let's start with Blecharz-Klin 26 -- 2015 B.
If you turn to Table 1.
A. Let me see. You gave me so many papers. Now I don't know which one it is.
Which exhibit number is it?
Q. It's the 2015 that I recently handed -- 85.

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A. 85. Thank you.
Q. Was there a statistically significant change in 5-HT signaling for the P5 and P15, which is 5 milligram per kilogram and 15 milligrams per kilogram? Is that right?
A. According to Table 1, there was not statistically significant changes, and this is in spinal cord.
But if you look at P15, there's quite a substantial increase. It goes from 88, and the units here are -- I don't see -- nanograms per grams tissue, all the way up to 107 nanograms per gram.
So biologically significant increase, but not statistically significant increase.
Q. What do you mean by a biologically significant increase?
A. Well, potentially biologically meaningful, but not significantly reliably increased.
Q. Okay. If you could turn to Blecharz-Klin --
A. I'm sorry, that was -- I'll

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clarify.
That was in 5-HIAA, which is a metabolite of serotonin. So I was reading the wrong line. I was reading below serotonin. I would caveat that. I was reading the wrong line.
Q. Serotonin is not bio -- did not show statistically significant changes?
A. Serotonin didn't, but -- serotonin, actually 5-HT, showed a linear trend upwards --
Q. Okay.
A. -- even it wasn't significantly increased.
Q. If you could turn to Blecharz-Klin 2016.
A. 2016.
Q. And that is exhibit --
A. 86, looks like.
Q. 86?
If you could turn to page 1161.
A. Okay.
Q. Table 1.
A. Yeah. So there serotonin is up at the 5 milligrams per kilogram dose, but

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not statistically significant.
The metabolite, the primary metabolite, 5-HIAA is significantly different between groups.
And there's trends towards differences in the 5-HIAA/5-HT ratio, which is a utilization ratio, not statistically significant.
Q. 5-HT was not statistically significant. And then even you're talking from an increase from 5-HT from control to P5 to P15, there's not a dose response from P5 to P15, correct?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: Well, there's an inverted U-dose response, so I don't know what you mean by not a dose response. There's still a dose response.
QUESTIONS BY MR. PADGETT:
Q. Sorry. If you'd turn to Blecharz 2019, which is Exhibit 87, I believe.

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If you look at Table 1, the serotonin levels were not -- there were no statistically significant differences for control P5 or P15, correct?
A. There are no statistically significant differences here, and this is in the hypothalamus. Different brain region.
(Pearson Exhibit 88 marked for identification.)
QUESTIONS BY MR. PADGETT:
Q. Okay. Dr. Pearson, I'm going to hand you what's been marked as Exhibit 90 and -- strike that.
I'm going to hand you what's been marked as Exhibit 88 and represent to you that this is a -- sorry.
Do you ever -- do you refer to the NIH as an authoritative body or organization with regard to standards of conducting scientific research?
MS. HUNT: Object to the form of the question.
You can answer.
THE WITNESS: The NIH on the whole, that's a fairly broad category.

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The NIH is a really, really widespread organization that is involved in funding research and conducting research.

NIH has organizations within it that has very, very specific standards for compliance within research, so I would say many of those organizations I would look to as authorities on research compliance and research ethics, if that's what you're asking about, yeah.

QUESTIONS BY MR. PADGETT:

Q. I'm going to represent to you that Exhibit 88 is off the NIH website, specifically a section on grants and funding, NIH central resource for grants and funding and for information.

Are you familiar with that document? Or that part of the NIH website?

A. I'm familiar that the NIH, through their grants offices, has these sorts of offices on rigor and transparency and research in funding, yes.

MS. HUNT: I'm sorry, I would

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just object. I'm not sure this is a complete exhibit.

QUESTIONS BY MR. PADGETT:

Q. On the second page of that exhibit it states, quote, "Two of the cornerstones of science advancement are rigor in designing and performing scientific research and the ability to reproduce biomedical research findings," period, end quote.

Do you agree with that statement?

A. I certainly agree with that statement.

But I want to extend this. This isn't referring to the fact that individual data points within research studies have to be reproduced in order for the research to be reliable.

They're referring to the fact that people need to be transparent about the way that they conduct their research so that other people can perform work similarly, or understand the way that people have performed their research, so that they can follow up

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and design their own research accordingly.

So we don't want to misconstrue what's being stated here. They're not saying that for -- in order for research to be considered reliable, that every single data point in everybody else's research has to be replicated in exactly the same way for it to be considered reliable. It's false equivalence.

Q. In the second -- and then the -- a sentence two -- two more after that one that we just discussed, it says, quote, "When a result can be reproduced by multiple scientists, it validates the original results and readiness to progress to the next phase of research," period, end quote.

Do you agree with that statement?

A. I agree with that statement.

But what defines a result doesn't mean that the result is -- that the study is performed in exactly the same way and the datum, or the exact data point, is exactly the same thing.

Q. At pages 65 to 66 of your

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report, you discuss prostaglandins?

A. Yes.

Q. You state that -- there on -- it's on page 66 -- that APAP's effects on prostaglandins are likely interconnected with other processes and also affected by APAP, and then you reference AM404 again.

Is it your opinion that any alleged effects on prostaglandins are the result of the AM404 metabolite?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: That is not what's meant by this paragraph.

QUESTIONS BY MR. PADGETT:

Q. What is meant by that paragraph in the reference to AM404?

A. So what's meant here is that acetaminophen's actions, mode of action, with respect to antinociceptive effects can involve prostaglandins. Its effects on neurodevelopment can also involve prostaglandins.

It's also saying that

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acetaminophen can act through AM404 and the endocannabinoid system and that these two path -- these different pathways can also intersect with each other. But it's not saying that prostaglandins necessarily involve AM404.

Q. Is an increase -- and you talk about spinophilin in the -- I think it was the...

A. Oh, cealix {phonetic} spinophilin, yeah.

Q. Yes.

A. A protein, yeah.

Q. Is it your opinion that an increase in spinophilin is a change seen in ASD or ADHD brains that has been accepted in the scientific community as a cause of ASD or ADHD?

A. Changes in synaptics, dendritic spines has been seen as sa pathological hallmark in a number of neurodevelopmental disorders, including ASD. But that particular protein isn't necessarily a diagnostic feature of those particular neurodevelopmental disorders.

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And that particular protein that you're discussing is involved in plasticity of dendritic spines.

Q. What is the function of the cerebellar vermis area of the brain?

A. The cerebellar vermis is just one anatomical location within the cerebellum.

The cerebellum in general is involved in a lot of functions, in motor behaviors, cognitive behaviors. It's recently been learned to be involved in a lot of emotional-related functions as well.

The vermis area of the cerebellum is -- I'm not particularly up on what it's actually involved with, but in general, again, the cerebellum has diverse functions ranging from emotion to cognition.

And its involvement in ASD and ADHD is -- is well -- it's linked to both conditions.

Q. I'm talking about specifically the cerebellar vermis area of the brain.

Do you know whether that -- changes in that region have -- are thought to

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be a plausible biomech -- mechanism -- biological mechanism of ASD or ADHD?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: My recollection is the vermis area of the cerebellum is just an interfaced area of the cerebellum, but I don't have deep expertise about the vermis itself of the cerebellum.

As I mentioned, the cerebellum is a very involved, very rich area of the brain that's -- that has very diverse functions.

I think Dr. Hollander would be able to give a much more direct and complete answer to that.

MR. PADGETT: We can take a short break. I may be near about done. The break may help facilitate that.

MS. HUNT: Party on.

VIDEOGRAPHER: The time right now is 4:43 p.m., and we're off the

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record.

(Off the record at 4:43 p.m.)

VIDEOGRAPHER: The time right now is 5:07 p.m., and we're back on the record.

MR. PADGETT: At this time we have no further questions and pass the witness.

CROSS-EXAMINATION

QUESTIONS BY MS. HUNT:

Q. I just have a few questions.

Dr. Pearson, you testified earlier that you were contacted by plaintiffs' counsel sometime in 2022.

Is that right?

A. That's right. I stated that I was contacted -- well, my answer shifted a little bit. I initially said 2023, and then I said 2022. I was a little bit confused.

Thinking about it more, I was initially contacted more accurately in June of 2022, but I didn't actually start working with plaintiffs' counsel until -- substantively until February of 2023. That's when I started having billable work.

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Q. Okay. And did any lawyer have input on the analysis or the conclusions of your study, Baker 2023?
A. No.
Q. And were you completely objective in rendering the results of your study?
A. Yes.
Q. Have you ever authored or worked on any studies at the behest of lawyers?
A. No.
Q. Dr. Pearson, do you recall your earlier testimony about translationally relevant APAP doses used in rodent studies?
A. Yes.
Q. Okay. And in general, is the translationally relevant dose for mice different than the translationally relevant dose for rats?
A. Mice and rats have different sensitivities to acetaminophen administration, so the answer to that would be to the affirmative. They can have different translationally relevant doses.

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Q. Okay. Can we turn to page 83 of your expert report? I think that should be...
A. Yes.
Q. Yes.
Dr. Pearson, can you tell me what animal was used in the Beck 2001 study?
A. Rats.
Q. How about Lichtensteiger 2015?
A. Rats.
Q. How about Klein 2020?
A. Rat.
Q. How about Rigobello 2021?
A. Also rats.
Q. And in your expert opinion, did these rat studies use translationally relevant APAP doses?
A. Yes.
Q. Finally, Dr. Pearson, did you rely on Dr. Baccarelli's opinions in terms of his review of the human epidemiological studies in rendering your opinion?
A. I did.
Q. And is the epidemiological literature analyzed by Dr. Baccarelli part of

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what has informed your work both in this litigation and outside of it?
A. Yes.
So to add on to that, so Dr. Baccarelli's expert report, which I reviewed and rely upon for my expert report, he uses the Bradford Hill approach. And the other approach that he uses, I rely upon that in my expert report. But also the epidemiological literature that he's reviewed, that also informs the scientific research that I perform.
So not his expert report, per se, but I'm just saying the epidemiological findings that acetaminophen is linked to these neurodevelopmental outcomes. I would not be performing preclinical literature -- preclinical research if there wasn't these findings themselves.
MS. HUNT: I have no more questions.
VIDEOGRAPHER: Off the record?
MR. PADGETT: Off the record.
VIDEOGRAPHER: The time right now --

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MR. PADGETT: Can I take a break? A short break?
VIDEOGRAPHER: The time right now is 5:10 p.m., and we're off the record.
(Off the record at 5:10 p.m.)
VIDEOGRAPHER: The time right now is 5:15 p.m., and we're back on the record.
REDIRECT EXAMINATION
QUESTIONS BY MR. PADGETT:
Q. Dr. Pearson, you used mice as the animal in the Baker 2023 study, correct?
A. That is correct.
Q. Okay. And you mentioned something about mice and rats having different sensitivities to APAP during Ms. Hunt's questioning.
Do you recall that?
A. Yes, I recall that.
Q. Okay. Do you believe that mice are a better model in terms of equivalency to humans in terms of animal research on acetaminophen?
MS. HUNT: Object to the form

of the question.

You can answer.

THE WITNESS: I think that both mice and rats are suitable for this line of research.

What I was stating before is that mice and rats have different sensitivity to hepatotoxic doses of acetaminophen.

QUESTIONS BY MR. PADGETT:

Q. Is the sensitivity for mice more akin to humans with regard to acetaminophen than rats compared to humans?

MS. HUNT: Object to the form of the question.

You can answer.

THE WITNESS: I've seen in the literature some people have said that mice can be more sensitive to modeling hepatotoxicity because lower doses of acetaminophen will cause hepatotoxicity in mice than rats.

In other words, it takes a higher dose -- it can, depending on the strain and the circumstances, it

can take a higher dose of acetaminophen in a rat to cause hepatotoxicity than a mouse.

But that does not mean it's a better model for understanding acetaminophen neurotoxicity, for instance. Both species can be suitable to understand neurotoxicity of acetaminophen.

MR. PADGETT: That's all the questions I have. Thank you for your time today.

THE WITNESS: Thank you.

VIDEOGRAPHER: The time right now is 5:18 p.m., and we're off the record.

(Deposition concluded at 5:18 p.m.)

– – – – – – –

CERTIFICATE

I, CARRIE A. CAMPBELL, Registered Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, Brandon Pearson, MS, Ph.D., was duly sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

CARRIE A. CAMPBELL,
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Dated: August 14, 2023

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
Brandon Pearson, MS, Ph.D. DATE

Subscribed and sworn to before me this
_____ day of _____, 20 _____.
My commission expires: _____

Notary Public

ERRATA

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